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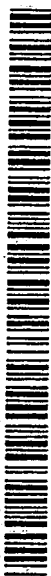


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(54) Title: SYSTEM AND METHOD FOR JOINT RESURFACE REPAIR

(57) Abstract:

# 1 SYSTEM AND METHOD FOR JOINT RESURFACE REPAIR

## 2 FIELD OF THE INVENTION

3 This invention relates to devices and methods for the repair of defects that occur  
4 in articular cartilage on the surface of bones, particularly the knee.

## 5 BACKGROUND OF THE INVENTION

6 Articular cartilage, found at the ends of articulating bone in the body, is typically  
7 composed of hyaline cartilage, which has many unique properties that allow it to function  
8 effectively as a smooth and lubricious load-bearing surface. However, when injured,  
9 hyaline cartilage cells are not typically replaced by new hyaline cartilage cells. Healing  
10 is dependent upon the occurrence of bleeding from the underlying bone and formation of  
11 scar or reparative cartilage called fibrocartilage. While similar, fibrocartilage does not  
12 possess the same unique aspects of native hyaline cartilage and tends to be far less  
13 durable.

14 Hyaline cartilage problems, particularly in knee and hip joints, are generally  
15 caused by disease such as occurs with rheumatoid arthritis or wear and tear  
16 (osteoarthritis), or secondary to an injury, either acute (sudden), or recurrent and chronic  
17 (ongoing). Such cartilage disease or deterioration can compromise the articular surface  
18 causing pain and further deterioration of joint function. As a result, various methods  
19 have been developed to treat and repair damaged or destroyed articular cartilage.

20 For smaller defects, traditional options for this type of problem include non-  
21 operative therapies (e.g., oral medication or medication by injection into the joint), or  
22 performing a surgical procedure called abrasion arthroplasty or abrasion chondralplasty.  
23 The principle behind this procedure is to attempt to stimulate natural healing. At the  
24 defect site, the bone surface is abraded, removing approximately 1 mm. or less using a  
25 high-speed rotary burr or shaving device. This creates an exposed subchondral bone bed  
26 that will bleed and will initiate a fibrocartilage healing response. Although this  
27 procedure has been widely used over the past two decades and can provide good short

1 term results, (1-3 years), the resulting fibrocartilage surface is seldom able to support  
2 long-term weight bearing, particularly in high-activity patients, and is prone to wear.

3 Another procedure, referred to as the "microfracture" technique, incorporates  
4 similar concepts of creating exposed subchondral bone. During the procedure, the  
5 cartilage layer of the chondral defect is removed. Several pathways or "microfractures"  
6 are created to the subchondral bleeding bone bed by impacting a metal pick or surgical  
7 awl at a minimum number of locations within the lesion. By establishing bleeding in the  
8 lesion and by creating a pathway to the subchondral bone, a fibrocartilage healing  
9 response is initiated, forming a replacement surface. Results for this technique are  
10 generally similar to abrasion chondralplasty.

11 Another known option to treat damaged articular cartilage is a cartilage transplant,  
12 referred to as a Mosaicplasty or osteoarticular transfer system (OATS) technique. This  
13 involves using a series of dowel cutting instruments to harvest a plug of articular cartilage  
14 and subchondral bone from a donor site, which can then be implanted into a core made  
15 into the defect site. By repeating this process, transferring a series of plugs, and by  
16 placing them in close proximity to one another, in mosaic-like fashion, a new grafted  
17 hyaline cartilage surface can be established. The result is a hyaline-like surface  
18 interposed with a fibrocartilage healing response between each graft.

19 This procedure is technically difficult, as all grafts must be taken with the axis of  
20 the harvesting coring drill being kept perpendicular to the articular surface at the point of  
21 harvest. Also, all graft placement sites must be drilled with the axis of a similar coring  
22 tool being kept perpendicular to the articular surface at the point of implantation. Further,  
23 all grafts must be placed so that the articular surface portion of these cartilage and bone  
24 plugs is delivered to the implantation site and seated at the same level as the surrounding  
25 articular surface. If these plugs are not properly placed in relation to the surrounding  
26 articular surface, the procedure can have a very detrimental effect on the mating articular  
27 surface. If the plugs are placed too far below the level of the surrounding articular  
28 surface, no benefit from the procedure will be gained. Further, based on the requirement  
29 of perpendicularity on all harvesting and placement sites, the procedure requires many

1 access and approach angles that typically require an open field surgical procedure.  
2 Finally, this procedure requires a lengthy post-operative non-weight bearing course.

3 Transplantation of previously harvested hyaline cartilage cells from the same  
4 patient has been utilized in recent years. After the cartilage is removed or harvested, it is  
5 cultured in the lab to obtain an increase in the number of cells. These cells are later  
6 injected back into the focal defect site and retained by sewing a patch of periosteal tissue  
7 over the top of the defect to contain the cells while they heal and mature. The  
8 disadvantages of this procedure are its enormous expense, technical complexity, and the  
9 need for an open knee surgery. Further, this technique is still considered somewhat  
10 experimental and long-term results are unknown. Some early studies have concluded that  
11 this approach offers no significant improvement in outcomes over traditional abrasion  
12 and microfracture techniques.

13 U.S. Patent No. 5,782,835 to Hart et al. discloses an apparatus and method for  
14 repair of articular cartilage including a bone plug removal tool, and a bone plug  
15 emplacement tool. The method of repairing defective articular cartilage includes the  
16 steps of removing the defective cartilage and forming a hole of sufficient depth at the site.  
17 A bone plug comprising intact bone and cartilage adhering thereto is removed from a  
18 bone lacking defective cartilage is placed in the hole at the site of the damage.

19 U.S. Patent No. 5,413,608 to Keller discloses a knee joint endoprosthesis for  
20 replacing the articular surfaces of the tibia comprising a bearing part which is anchored  
21 on the bone having an upper bearing surface and a rotatable plateau secured on the  
22 bearing surface and forming a part of the articular surface to be replaced. A journal rises  
23 from the bearing surface and cooperates with a bore in the plateau to provide lateral  
24 support.

25 U.S. Patent No. 5,632,745 to Schwartz describes a method of surgically  
26 implanting into a site a bio-absorbable cartilage repair assembly. The assembly includes  
27 a bio-absorbable polygonal T-shaped delivery unit having radial ribs to be mounted in the  
28 removed area and a porous bio-absorbable insert supported by and in the delivery unit.  
29 The method comprises the steps of preparing the site to receive the assembly by

1 removing a portion of the damaged cartilage and preparing the site to receive the  
2 assembly by drilling and countersinking the bone. The assembly is inserted and seated  
3 using an impactor in the drilled and countersunk hole in the bone until the assembly is  
4 flush with the surrounding articular surface.

5 U.S. Patent No. 5,683,466 to Vitale illustrates an articular joint surface  
6 replacement system having two opposing components. Each component has a tapered  
7 head piece for covering the end of a bone and for acting as an articular surface, an  
8 integrally formed screw stem of sufficient length to extend into the bone and inwardly  
9 angled bone grips on the underside of the head piece to allow fixation to the bone by  
10 compression fit. The partially spherical convex shaped exterior of the first component  
11 complements the partially spherical concave shaped exterior of the second component.

12 U.S. Patent No. 5,702,401 to Shaffer discloses an intra-articular measuring device  
13 including a hollow handle defining a first passageway and a hollow tube having a second  
14 passageway extending from the handle, the hollow tube carrying a projection at its distal  
15 end for seating on a fixed site and a probe disposed at the distal end of the hollow tube  
16 which may be directed to a second site, to enable measurement of the distance between  
17 the first and second sites.

18 U.S. Patent No. 5,771,310 to Vannah describes a method of mapping the three-  
19 dimensional topography of the surface of an object by generating digital data points at a  
20 plurality of sample points on said surface, each digital data point including a property  
21 value and a position value corresponding to a particular point representing the properties  
22 of the surface of the object. A 3-D transducer probe (e.g., a digitizer) is moved on or  
23 over the surface along a random path, and the sample points are digitized to generate a  
24 real-time topography or map on a computer screen of selected properties of the object,  
25 including without limitation, surface elevation, indentation stiffness, elevation of sub-  
26 surface layers and temperature.

27 Prosthetics for total knee replacement (TKR), whereby the entire knee joint or a  
28 single compartment of the knee joint is replaced can be a common eventuality for the  
29 patient with a large focal defect. Although these patients are also managed with anti-

1 inflammatory medications, eventual erosion of the remaining articular cartilage results in  
2 effusion, pain, and loss of mobility and/or activity for the patient. Problems encountered  
3 after implanting such prostheses are usually caused by the eventual loosening of the  
4 prosthetic due to osteolysis, wear, or deterioration of the cements used to attach the  
5 device to the host bones. Further, some prostheses used are actually much larger than the  
6 degenerated tissue that needs to be replaced, so that extensive portions of healthy bone  
7 are typically removed to accommodate the prostheses. Patients who undergo TKR often  
8 face a long and difficult rehabilitation period, and the life span of the TKR is accepted to  
9 be approximately 20 years. Accordingly, efforts are made to forgo the TKR procedure  
10 for as long as possible.

11 Accordingly, there is a need for an improved joint surface replacement system  
12 that would be effective in restoring a smooth and continuous articulating surface and that  
13 would also be as durable as the former hyaline cartilage surface, within the context of a  
14 minimally invasive procedure that allows for a nearly immediate return to activity,  
15 restoration of lifestyle, and pain relief.

#### 16 SUMMARY OF THE INVENTION

17 The present invention provides tools and methods for mapping and measuring the  
18 articular surface of a joint (or of any bony surface) and for fabricating a prosthetic device  
19 based on this recorded data.

20 In one method consistent with the invention, once the defect of the chondral  
21 surface has been identified, a guide pin is inserted arthroscopically. A fixation screw  
22 having a tapered distal tip and an aggressive distal end thread form is then driven into the  
23 subchondral bone in relation to a reference axis that is approximately central to the  
24 defect. The fixation device also serves to define a tangent point to the surrounding  
25 articular surface. The screw is driven by a socket type driver that engages a hex-shaped  
26 proximal extension. A further cylindrical proximal extension of the screw (or other  
27 mating feature, e.g., a recess in the screw) that eventually serves as a fixation element for  
28 the surface prosthetic is at this time concealed with a cover (or other mating feature  
29 corresponding to the mating feature of the screw, e.g., a plug for mating with a screw

1 having a recess as its mating feature) having a radiused proximal end. One or more  
2 milled slots run the length of the uniform diameter portion of the screw.

3 Under arthroscopic view, the screw depth is adjusted so that the radiused cover  
4 surface is positioned tangent to the radius that defines the existing articular surface. At  
5 this time, the guide pin is removed and the knee is articulated. The depth positioning of  
6 the radiused cover establishes an origin or reference point for all future measuring,  
7 cutting, and prosthetic machining operations. Arthroscopic examination is carried out to  
8 confirm positioning.

9 A measuring tool is inserted on the reference axis. A central element of the  
10 measuring tool is a static post that establishes the axial location of origin. By rotating  
11 the outer arm or outrigger of the measuring tool relative to the static post while also  
12 maintaining contact with the articular surface, an axial displacement or Z dimension can  
13 be established relative to the origin for any point along the known radial sweep of the  
14 outrigger to determine the final geometry of the prosthetic surface which fits within the  
15 defect. These Z dimensions can be recorded in real time with conventional dial gauge  
16 indicators, or with digital recording devices, or by using marking techniques. Although  
17 numerous points may be taken, ideally a minimum number of points are taken to  
18 accurately define the target articular surface.

19 Locating surfaces or features created on the screw, (or alternatively, on the radius  
20 cover, as described in alternative embodiments herein), correlate to some surface or  
21 feature on the measuring tool and allow the measurement of the rotational position of the  
22 points about the axis with respect to the locating surfaces. Data recorded during the  
23 mapping procedure can then be entered into parametric engineering design software or  
24 similar algorithm to define a three dimensional surface matched to the bearing surface  
25 geometry to be implanted and reproduce the anatomic contours mapped.

26 An alternative measuring device for obtaining the articular surface dimension  
27 includes an outer marking element and an inner recording element. The marking element  
28 includes a sharp indenting mechanism which when pressed by the surgeon creates a  
29 depression or mark in the relatively soft surface of the recording element, which deforms

1 at these marked points so that they can be utilized as patient data. The recording  
2 element also includes a surface that corresponds to the surface of the proximal extension  
3 of the fixation screw. During the mapping procedure, data points are established of the  
4 rotational position of the mapped articular surface relative to the screw. These data  
5 points are translated to the implant geometry so that the accurate rotational location of the  
6 implant relative to the screw is maintained.

7 In order to secure the implant to the fixation screw, a precision taper (or other  
8 component of a mating feature) is machined into a protrusion (or other component of a  
9 mating feature) on the back of the device. The implant may be constructed of cobalt  
10 chromium, or other materials. The implant may also include a slight outward taper or  
11 protrusion along the diametrical surface to enhance load bearing or load transfer  
12 properties of the implant to surrounding bone. Additionally, a series of radial cuts may  
13 create surfaces that increase resistance of the implant to rotational forces. These features  
14 may be located around the outer diameter of the implant.

15 In another aspect, the invention includes a compass instrument for measurement  
16 and surface preparation of the implant target site subsequent sizing of the implant. This  
17 compass instrument is configured so that it can be delivered to the site arthroscopically,  
18 and when coupled to the axis defined by the guide pin it can be used for measuring and  
19 cutting operations.

20 In another embodiment, the compass instrument consists of a handle, a cannulated  
21 shaft that extends through the handle, and a cannulated distal offset arm configured to  
22 serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades,  
23 or measuring probes.

24 With the guide pin advanced through the instrument shaft, when fitted with a  
25 blade, a fixed length from the rotational or reference axis to the cutting blade's cutting  
26 surface is established. This defines the radius that is effected as the instrument is rotated  
27 around the guide pin, and corresponds to the overall diameter of the implant. This sharp  
28 cutting blade is used to circumscribe and cleanly cut the surrounding articular cartilage.



1           In another aspect, the invention features a bone cutting or scoring instrument  
2   whereby the bone-cutting instrument is positioned on the guide pin reference axis and is  
3   used to prepare the target site to match in configuration and dimension the contacting  
4   surface of the implant. The matching fit between the bone surfaces of the prepared  
5   target site and the bone contacting surfaces of the implant can advantageously ensure  
6   long term clinical results with the implant, as poor quality of fit between bone surfaces  
7   and bone contacting surfaces of traditional orthopedic prosthetic devices has been noted  
8   to contribute to early clinical failures.

9           Following fabrication of the implant, a second surgical procedure is performed.  
10   The radiused cover is removed exposing a precision taper (or, alternatively, the cover  
11   may be removed during the first procedure). A pin with a distally mounted element is  
12   placed through the central lumen of the fixation screw so that the distally mounted  
13   element is secured into the screw. This element carries one or more suture strands that  
14   now trail from the fixation screw. The sutures are then threaded through the implant and  
15   a knot or bead may be created proximal to the implant. By continuing to manipulate and  
16   tension the suture strands, the implant can be brought coaxial to the fixation screw. Once  
17   coaxial, the implant is aligned via engagement of the keyed elements and driven into  
18   place with a plastic driving rod and mallet. Finally, through the guide aperture on the  
19   surface of the implant, bone cement may be injected to enhance the contact surface  
20   between the implant and the subchondral bone.

21           In another aspect, the invention further features a driver whereby the implant is  
22   connected to the driver via a holder and a tether element, such as a suture or wire. The  
23   implant and the driver are then inserted arthroscopically. Tension is then applied to the  
24   tether element so that the implant is drawn back and seated on the driver. The implant  
25   can then be controllably delivered to the prepared target site. The seat portion of the  
26   driver may comprise a material that may be impacted to seat the implant without  
27   damaging the implant surface.

## DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary side view of a knee having therein an exemplary assembled fixation device and implant of the joint surface repair system surgically implanted by the method in one embodiment of the present invention;

FIG. 2a is an exploded side view of an exemplary fixation screw and hex-shaped proximal extension in one embodiment of the present invention;

FIG. 2b is an exploded perspective view of an exemplary fixation screw and hex-shaped proximal extension in one embodiment of the present invention;

FIG. 3a is a side view of an exemplary assembled fixation screw and hex shaped extension in one embodiment of the present invention;

FIG. 3b is an exploded perspective view of another exemplary fixation screw and implant in one embodiment of the present invention;

FIG. 4a is a perspective view of the upper surface of an exemplary implant in one embodiment of the present invention;

FIG. 4b is a side view of an exemplary implant in one embodiment of the present invention;

FIG. 4c is a perspective view of the lower surface of an exemplary implant in one embodiment of the present invention;

FIG. 5a is a side view of an exemplary assembled fixation device and implant in one embodiment of the present invention;

FIG. 5b is a perspective view of an assembled fixation device and implant in one embodiment of the present invention;

FIG. 5c is a perspective view of the upper surface of an exemplary implant, in one embodiment of the present invention;

FIG. 5d is a perspective view of the lower surface of an exemplary implant, in one embodiment of the present invention;

1           FIG. 6a is a sectional view of a knee having damaged articular cartilage, showing  
2   an exemplary guide pin drilled into the central portion of the defect and an arthroscope  
3   being disposed adjacent thereto, in a surgical procedure consistent with one embodiment  
4   of the present invention;

5           FIG. 6b is a side view of the distal tip of an exemplary drill device for boring a  
6   pilot hole to receive an exemplary fixation screw, in one embodiment of the present  
7   invention;

8           FIG. 7a is a sectional view of a knee having damaged articular cartilage, showing  
9   an exemplary fixation screw being driven into the defect by an exemplary socket type  
10   driver arranged on the guide pin, in a surgical procedure consistent with one embodiment  
11   of the present invention;

12          FIG. 7b is a side view of the exemplary fixation screw, socket type driver and  
13   guide pin of FIG. 7a, illustrating the hex shaped proximal extension in a cross-sectional  
14   view, in a surgical procedure consistent with one embodiment of the present invention;

15          FIG. 8a is a perspective view of a knee having damaged articular cartilage,  
16   showing an exemplary fixation screw and hex-shaped proximal extension implanted in  
17   the defect after removal of an exemplary socket type driver and guide pin, in a surgical  
18   procedure consistent with one embodiment of the present invention;

19          FIG. 8b is a sagittal view of the exemplary fixation screw and hex-shaped  
20   proximal extension of FIG. 8a implanted in the defect after removal of an exemplary  
21   socket type driver and guide pin, in a surgical procedure consistent with one embodiment  
22   of the present invention;

23          FIG. 8c is a perspective view of an exemplary fixation screw, proximal extension  
24   and cover, in one embodiment of the present invention;

25          FIG. 9a is a sectional view of an exemplary fixation screw and hex-shaped  
26   proximal extension implanted in the defect with the exemplary guide pin replaced and an

1 exemplary measuring tool arranged thereon, in a surgical procedure consistent with one  
2 embodiment of the present invention;

3 FIG. 9b is a side partial cross-sectional view of the exemplary fixation screw and  
4 hex-shaped proximal extension of FIG. 9a implanted in the defect with the exemplary  
5 guide pin replaced and an exemplary measuring tool arranged thereon, in a surgical  
6 procedure consistent with one embodiment of the present invention;

7 FIG. 9c is a perspective view of an exemplary fixation screw and proximal  
8 extension, with the cover removed, in one embodiment of the present invention;

9 FIG. 10a is a sectional view of an exemplary fixation screw and hex-shaped  
10 proximal extension implanted in the defect, after removal of the hex-shaped proximal  
11 extension, with an exemplary pin and suture strands placed therethrough, in a surgical  
12 procedure consistent with one embodiment of the present invention;

13 FIG. 10b is a side partial cross-sectional view of the exemplary fixation screw and  
14 hex-shaped proximal extension of FIG. 10a, implanted in the defect, with an exemplary  
15 pin and suture strands placed therethrough, in a surgical procedure consistent with one  
16 embodiment of the present invention;

17 FIG. 11a is a sectional view of an exemplary fixation screw implanted in the  
18 defect, with an exemplary pin and suture strands placed therethrough, showing the  
19 implanted fixation screw with the implant being tensioned on the suture strands, in a  
20 surgical procedure consistent with one embodiment of the present invention;

21 FIG. 11b is a partial cross-sectional view of the exemplary fixation screw of FIG.  
22 9a implanted in the defect, showing the implant positioned in the interchondular notch, in  
23 a surgical procedure consistent with one embodiment of the present invention;

24 FIG. 12 is a sectional view of an exemplary fixation screw implanted in the  
25 defect, wherein, after placement of the implant and removal of the suture strands, the  
26 implant is driven into place with an impactor and hammer, in a surgical procedure  
27 consistent with one embodiment of the present invention;

1           FIG. 13 is a side cross-sectional view of an exemplary fixation screw implanted in  
2     the defect, after placement of the implant, wherein, after removal of the impactor and  
3     hammer, cement is injected between the implant and the bone, in a surgical procedure  
4     consistent with one embodiment of the present invention;

5           FIG. 14a is a schematic representation of the two datum curves used to define a  
6     patient-specific three-dimensional surface for construction of the articular or lower  
7     surface of an implant in one embodiment of the present invention;

8           FIG. 14b is a top view of an exemplary hex-shaped proximal extension in one  
9     embodiment of the present invention;

10          FIG. 14c is a perspective view of the bone-contacting or upper surface of an  
11     exemplary implant, in one embodiment of the present invention;

12          FIG. 15a is a perspective view of an exemplary compass instrument, in one  
13     embodiment of the present invention;

14          FIG. 15b is a perspective view of the distal offset arm of an exemplary compass  
15     instrument and cutting blade to be mounted thereon, in one embodiment of the present  
16     invention;

17          FIG. 15c is a perspective view of an exemplary driver, showing an exemplary  
18     implant on an exemplary tether element, in one embodiment of the present invention;

19          FIG. 15d is a perspective view of an exemplary driver, showing an exemplary  
20     implant tensioned on an exemplary tether element, in one embodiment of the present  
21     invention;

22          FIG. 16 is a perspective view of an exemplary compass instrument and cutting  
23     blade mounted on an exemplary guide pin, in one embodiment of the present invention;

24          FIG. 17a is a perspective view of another exemplary cutting blade, in one  
25     embodiment of the present invention;

26          FIG. 17b is a perspective view of an exemplary measuring probe, in one  
27     embodiment of the present invention;

1           FIG. 17c is a perspective view of an exemplary multi-faced blade mounted in the  
2   distal offset arm of an exemplary compass instrument, in one embodiment of the present  
3   invention;

4           FIG. 18a is a perspective view of an exemplary site preparation and cutting  
5   device, in one embodiment of the present invention;

6           FIG. 18b is a cross sectional view of the exemplary site preparation and cutting  
7   device of FIG. 18a, in one embodiment of the present invention;

8           FIG. 18c is a perspective view of another exemplary site preparation and cutting  
9   device, in one embodiment of the present invention;

10          FIG. 18d is a side view of another exemplary site preparation and cutting device,  
11   in one embodiment of the present invention;

12          FIG. 18e is a perspective view of another exemplary site preparation and cutting  
13   device, in one embodiment of the present invention;

14          FIG. 19a is a sectional view of the upper surface of an exemplary implant, in one  
15   embodiment of the present invention;

16          FIG. 19b is a side view of a portion of the exemplary implant of FIG. 19a, in one  
17   embodiment of the present invention;

18          FIG. 19c is a perspective view of the upper surface of the exemplary implant of  
19   FIG. 19a, in one embodiment of the present invention;

20          FIG. 19d is an exploded perspective view of another exemplary implant with  
21   taper lock ring, washer and suture, in one embodiment of the present invention;

22          FIG. 19e is a top perspective view of the exemplary implant of FIG. 19d seated in  
23   the taper lock ring, in one embodiment of the present invention;

24          FIG. 19f is a bottom perspective view of the exemplary implant of FIG. 19d  
25   seated in the taper lock ring, with washer and suture, disposed within an incision near the  
26   defect site, in one embodiment of the present invention;

1 FIG. 19g is a perspective view of the exemplary implant of FIG. 19d seated in the  
2 taper lock ring, with washer and suture, wherein the suture is threaded through an  
3 aperture at the distal end of a seating tool, at a first point in time during the process of  
4 seating the implant into the defect site, in one embodiment of the present invention;

5 FIG. 19h is another perspective view of the exemplary implant of FIG. 19d seated  
6 in the taper lock ring, with washer and suture, wherein the suture is threaded through an  
7 aperture at the distal end of a seating tool, at a second point in time during the process of  
8 seating the implant into the defect site, in one embodiment of the present invention;

9 FIG. 19i is another perspective view of the exemplary implant of FIG. 19d seated  
10 in the taper lock ring, wherein the distal end of a seating tool is disposed onto the  
11 implant, at a third point in time during the process of seating the implant into the defect  
12 site, in one embodiment of the present invention;

13 FIG. 20a is a perspective view of an exemplary inner recording element of an  
14 exemplary measuring device, in one embodiment of the present invention;

15 FIG. 20b is a perspective view of an exemplary outer marking element of an  
16 exemplary measuring device, in one embodiment of the present invention;

17 FIG. 20c is a cross-sectional perspective view of an exemplary measuring device  
18 showing an exemplary inner recording element and an exemplary outer marking element,  
19 in one embodiment of the present invention;

20 FIG. 20d is an exploded perspective view of another exemplary measuring device,  
21 in one embodiment of the present invention;

22 FIG. 20e is a perspective view of the exemplary measuring device of FIG. 20d,  
23 illustrating an exemplary scroll alignment feature, in one embodiment of the present  
24 invention;

25 FIGS. 20f and 20g are side views of the exemplary measuring device of FIG. 20d  
26 illustrating the translational motion of the handle with respect to the tip of the device, in  
27 one embodiment of the present invention;

1           FIG. 20h is a perspective view of the distal end of the exemplary measuring  
2 device of FIG. 20d, in one embodiment of the present invention;

3           FIG. 20i is a perspective view of the distal end of the exemplary measuring device  
4 of FIG. 20d with outer element, disposed upon the inner element engaging a mating  
5 feature of the screw, in one embodiment of the present invention;

6           FIG. 21 is a perspective view of an exemplary unitary implant, in one  
7 embodiment of the present invention;

8           FIG. 22 is a perspective view of a defect site with a keyed aperture for receiving  
9 the exemplary unitary implant of FIG. 21, in one embodiment of the present invention;

10          FIG. 23 is a perspective view of an exemplary composite implant, in one  
11 embodiment of the present invention;

12          FIG. 24 is a perspective view of another exemplary composite implant, in one  
13 embodiment of the present invention;

14          FIG. 25 is a perspective view of an exemplary implant illustrating the geometry of  
15 said implant for use in an algorithm for establishing minimum implant thickness, in one  
16 embodiment of the invention; and

17          FIG. 26 is a perspective view of an exemplary implant illustrating the geometry of  
18 said implant for use in an algorithm for establishing minimum implant thickness, in one  
19 embodiment of the invention.

## 20                   DETAILED DESCRIPTION OF THE EMBODIMENTS

21          As an overview, FIG. 1 shows a surgically implanted articular joint surface repair  
22 system consistent with the present invention. As shown, the assembled fixation device  
23 includes fixation screw 10, implant 40, and anchoring pin 5, implanted in the defect in the  
24 medial femoral chondral surface 55 of knee 50. Implant 40 is configured so that bearing  
25 or bottom surface 41 of the implant reproduces the anatomic contours of the surrounding  
26 articular surface of the knee 50.



1           As illustrated in FIGS. 2a, 2b and 3a, fixation screw 10 comprises threads 12  
2   running the length of the screw from tapered distal tip 11 to hex-shaped drive 15. In the  
3   embodiment shown, the screw includes a tapered distal end 11, and aggressive distal  
4   threads 12, so that, as screw 10 is driven into the subchondral bone 100 (as shown in FIG.  
5   7a) the screw dilates open and radially compress the subchondral bone, increasing its  
6   local density and thereby increasing the fixation strength of the screw. The screw 10 may  
7   taper down to the distal end 11, and the diameter of the screw may become greater and  
8   more uniform at the center thereof, so that adjustment of the depth of the screw 10 with  
9   respect to the subchondral bone 100 does not significantly further increase or decrease  
10   the compression of the subchondral bone.

11           One or more milled slots 13 run the length of the uniform diameter portion of the  
12   screw 10. Slots 13 ensure that as healing or tissue in-growth begins, migrational or  
13   rotational movement of the screw is inhibited. The screw 10 is configured to be driven  
14   by a female or socket type driver 2 as shown in Fig. 7b, which engages a hex-shaped  
15   drive 15 located toward the proximal end 17 of the screw. A cylindrical proximal  
16   extension 14 (which may, alternatively, be a recess 303 which mates with a plug or other  
17   protrusion on the implant surface, as shown in FIG. 8c) extends from hex-shaped drive  
18   15, which eventually serves as a fixation element for surface prosthetic implant 40.  
19   Through hole 16 runs through the central axis of the screw. Hex-shaped cover 30 (which  
20   may, alternatively, be a plug 301, for mating with a fixation element 302 having a recess,  
21   as shown, e.g., in FIGS. 3b, 8c, and 9c, and described in the following paragraph) is  
22   configured to engage the cylindrical proximal extension 14 of the screw 10 to prevent  
23   exposure of the cylindrical extension from inadvertent contact or damage. The hex-  
24   shaped cover 30 is finished with a radiused proximal end 31 that assists in the visual  
25   determination of the correct depth setting of the screw. Through hole 32 in the hex-  
26   shaped cover 30 corresponds with through hole 16 in the fixation screw 10.

27           Alternatively, as shown in FIGS. 3b, 8c, and 9c, the female-shaped cover may  
28   instead be a plug 301 having a male-shaped mating component 305, for mating with a  
29   fixation element 302 of a screw 10' having a recess 303. Additionally, the shape of the

1 cover and plug, or other recessed, protruding, or mating components may be other than  
2 hexagonal, and those in the art will recognize that one of any number of shapes or  
3 configurations for such components may be employed in a device or method consistent  
4 with the invention.

5 Also, while many of the components described herein are cannulated, having  
6 guide apertures, through holes, and/or central lumina along their length, for disposing  
7 such components about a guide rod for proper location of the components with respect to  
8 the articular surface, it should be recognized that a suture 313 or other flexible element,  
9 or other guide feature may be used in place of a guide rod, or a guide rod or wire may be  
10 eliminated altogether from one or more steps consistent with the invention described  
11 herein. As shown in FIG. 8c, the suture 313 may be fixedly or removably attached to the  
12 plug 301.

13 As shown in FIGS. 4a, 4b and 4c, implant 40 comprises lower bearing surface 41,  
14 top surface 42 and protrusion 45 located centrally on the bottom surface. As the top  
15 surface 42 of the implant 40 is not a bearing surface, and instead is fixed into subchondral  
16 bone 100, a series of stepped machine cuts 43 following the contours of the defect are  
17 created. By creating stepped machine cuts 43 a contoured contact surface matching the  
18 defect in the subchondral bone 100 is created. This contact surface results in an increased  
19 surface area that should enhance resistance to loosening of the implant 40 via rotational  
20 or translational loading. In the illustrated embodiment, the stepped cuts are shown as  
21 square cross-section cuts, but the cuts may be circular, triangular, or another  
22 configuration.

23 In order to secure the implant 40 to the fixation screw 10, precision taper 44 is  
24 machined into or onto a protrusion 45 on the top surface 42 of the implant. The  
25 precision taper 44 is configured to engage the cylindrical proximal extension 14 of the  
26 screw 10, once the hex-shaped cover 30 has been removed therefrom. Taper 44 may be  
27 mated with extension 14 so that a friction fit is provided between these surfaces. The  
28 assembled fixation device is shown in FIGS. 5a and 5b. Alternatively, other engagement  
29 mechanisms such as snap-fits, press-fits, threads, or coupling elements, for example, may

1 also be used. In one embodiment, leading pin 47 arranged on the protrusion 45 assists  
2 penetration into subchondral bone. Also, in one embodiment, guide aperture 46 passes  
3 through the top 42 and bottom 41 surfaces of the implant 40, just slightly off center of the  
4 reference axis 20A. Alternatively, guide aperture 46 may be located in the center of the  
5 implant 40 and corresponds to through hole 16 running through the central lumen in the  
6 fixation screw 10. Bone cement may be injected through guide aperture 46 on the  
7 surface of the implant 40 and through hole 16 in the fixation screw 10, to enhance the  
8 contact surface between the device and the subchondral bone. In one embodiment, the  
9 implant is constructed of cobalt chromium, although other materials may be used,  
10 including implantable plastics. Additionally, biologically active coatings or surface  
11 treatments (e.g., to enhance bone ingrowth or improve wear properties) may be utilized or  
12 combined as laminates, particularly with respect to the bearing surfaces and bone  
13 contacting surfaces. Further exemplary materials that may be used in fabricating an  
14 implant consistent with the invention are described hereinbelow.

15 As shown in FIG. 3b, it is noted that precision taper 44 may be a male-shaped  
16 component 304 instead of the above-described female component 44. In this  
17 configuration, the male-shaped component 304 of the implant 40' is configured for  
18 mating with a fixation element 302 of the screw 10' having a recess 303 adapted to  
19 receive the male-shaped component 304.

20 By way of example, FIGS. 6a-13 depict one exemplary joint surface methodology  
21 of the present invention. FIG. 6a shows a focal defect 1 of the articular surface 55 of the  
22 femoral chondyle bone of the knee 50. This defect is identified by arthroscope 25  
23 inserted in the area of the defect 1 during a diagnostic arthroscopy or surgical  
24 arthroscopy. The disclosed surgical intervention begins by drilling a guide pin 20  
25 defining reference axis 20A into the central portion of the defect 1 via an incision 200  
26 typical of arthroscopic procedures. Placement of this pin may be done using visual,  
27 freehand techniques, or may be located centrally by using outer element 71 of a  
28 measuring tool 70 (as shown in FIGS. 9a and 9b), or other aiming device or technique, to  
29 define a center. This reference axis 20A serves to establish a working axis located central

1 to the defect 1 for the procedures that follow, and arthroscope 25 may be used to view the  
2 joint for purposes of establishing a reference axis 20A generally perpendicular to and  
3 bisecting the existing articular surface 55 defined by radii 60 and 61, as shown in FIG.  
4 8b. Referring to FIG. 7a, 7b, 8a and 8b, fixation screw 10 and hex-shaped cover 30 are  
5 driven into the defect 1 in the subchondral bone 100 by socket-type driver 2 mounted  
6 over (i.e., about) guide pin 20 located on reference axis 20A. Under arthroscopic view,  
7 the depth of fixation screw 10 may be adjusted by driver 2 so that the bottom of the  
8 radiused surface 31 of the hex-shaped cover 30 is positioned tangent to the radii 60 and  
9 61 that define the existing articular surface 55. The guide pin 20 is removed and the knee  
10 50 is articulated through its range of motion to ensure that the height of the radiused  
11 surface 31 of the hex-shaped cover 30 is proper, since the prosthetic surface 41 of the  
12 implant 40 is created also to be tangent to this radiused surface 31. The depth positioning  
13 of the radiused surface 31 of the hex-shaped cover 30 establishes a point of origin or a  
14 reference point for all future measuring and machining operations. Arthroscopic  
15 examination may be carried out from multiple arthroscopic views to confirm positioning.

16 A drill mechanism 306, as illustrated in FIG. 6b, may be used to bore a pilot hole  
17 for receiving a fixation screw 10 (as shown, e.g., in FIGS. 2a, 2b and 3a). As shown, the  
18 drill may have a shank portion 307 and a bit portion 308. The bit portion 308 may  
19 include a spiral or parabolic fluted tip 309 having proximal 310, medial 311, and distal  
20 312 portions. The root diameter at the medial portion 311 is substantially equal to the  
21 diameter of the fixation screw 10, and the diameter decreases as the distal portion 312  
22 tapers away from the shank 307. The proximal portion 310 of the bit 308 may be used as  
23 a visual indicator during drilling, to determine the point at which the proper bore depth  
24 has been attained. The drill mechanism may have a central lumen (not shown) having a  
25 diameter slightly greater than the diameter of the guide pin 20 (as illustrated in FIG. 6a)  
26 running along its length, so that, with the guide pin 20 in place, the drill 306 may be  
27 disposed about the guide pin 20 during drilling to ensure proper location of the pilot hole  
28 with respect to the articular surface 55. Alternatively, a self-drilling or self-tapping  
29 screw, may be used, as those skilled in the art will recognize.

1 For surface preparation and accurate measurement of the implant site and the  
2 subsequent sizing of the implant, instrument 120 is provided. The compass instrument  
3 120 may be configured to serve as a mounting tool for a number of functional blades or  
4 tips and when located about the axis 20A, via guide rod 20, may be used for measuring  
5 and cutting operations. In the embodiment shown in FIG. 15a, compass instrument 120  
6 includes handle 110, a cannulated shaft 111 that extends through the handle, and a  
7 cannulated distal offset arm 112. The instrument may be rigid in construction and may  
8 be a durable reusable and resterilizable instrument. The distal offset arm 112 is  
9 configured so that it can be introduced into a site through an incision 200 typical of an  
10 arthroscopic procedure. Once the distal offset arm 112 has fully penetrated the incision  
11 and enters the site, shaft 111 can be angularly repositioned so that it becomes more  
12 coaxial to the reference axis 20A and advanced in-line with the reference axis 20A  
13 towards the implant target site. While performing this maneuver to position the  
14 compass instrument 120, the guide pin 20 should be removed from its position in the  
15 defect 1. When compass 120 is in its proper position at or near the implant target site, the  
16 guide pin 20 is delivered through the instrument cannulation 113, re-establishing the  
17 working (reference) axis 20A used to define the implant geometry.

18 Referring to FIG. 15b, within offset arm 112 is a slotted surface 114 for engaging  
19 a series of cutting blades 121, boring blades 124, or measuring probes 122. The slots 115  
20 are configured so that said series of cutting blades 121, boring blades 124 (FIG. 17c),  
21 measuring probes 122, 123 (FIGS. 17a, 17b), or like elements may be partially  
22 constrained or fixed in position such that they may be adjusted linearly along the length  
23 of the slotted surface 114 over a defined distance of travel. Intersecting the plane of  
24 travel defined by slotted surface 114 and slots 115, is the cannulation 113.

25 As illustrated in FIG. 16, when fitted with a cutting blade 121, and with the guide  
26 pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes  
27 through a closely sized hole 116 in the cutting blade, the blade's position becomes fully  
28 constrained. When constrained in this fashion, a fixed length from the rotational or  
29 reference axis 20A to the cutting surface 117 of cutting blade 121 is established. This

1 defines the radius that is effected as the instrument 120 is rotated around the guide pin 20,  
2 and corresponds to the overall diameter of the implant 40 that is delivered to the fully  
3 prepared site. The cutting blade 121 is used to circumscribe and cleanly cut the  
4 surrounding articular cartilage.

5 In an alternative embodiment, as shown in FIGS. 17a and 17b, blade 123 and  
6 measuring probe 122, respectively, may have multiple holes 118 that defines that  
7 probe/blade's functional diameter. In addition, the blades may be specifically configured  
8 so that staged or sequential cuts of varying depths and diameters can be performed within  
9 the procedure. Also, such a blade can be configured by providing a readable scale 119  
10 corresponding to the hole 118 pattern, so that the surgeon may determine and set the  
11 appropriate diameter as needed by positioning the guide pin 20 in the corresponding hole.  
12 As the readable scale 119 may be located on the blade 123 with respect to the blade's  
13 cutting surface 117, a high degree of positional accuracy may be achieved as the scale  
14 may be defined specifically for each type of blade. This approach creates an inexpensive  
15 means of providing sharp blades of varying diameters and varying blade types without a  
16 large inventory of size- and type-specific blades. Referring to FIG. 17b, rounded tip 109  
17 of measuring probe 122 can be used to determine the appropriate diameter and can be  
18 similarly sized and secured in the compass instrument 120. The tip 109 may be rounded  
19 to prevent marring of the articular surface. FIG. 17c shows a boring bit or bone cutting  
20 blade 124 with multiple cutting surfaces 107 and 108 configured in this fashion.

21 Turning now to FIGS. 9a and 9b, with the guide pin 20 replaced, a measuring tool  
22 70 is inserted so that the reference axis 20A is utilized. A central element of the  
23 measuring tool 70 is a post 75 that is static, establishes the axial location of the point of  
24 origin 80, and mates with a rotational location feature within the screw 14. By rotating  
25 the outer arm or outrigger 71 of the measuring tool 70 relative to the static post 75 while  
26 also maintaining contact with the articular surface 55, an axial displacement or Z  
27 dimension can be established relative to the point of origin 80 for any point along the  
28 sweep of the outrigger. Each such Z dimension may be recorded in real time with  
29 conventional dial gauge indicators 72 or with a digital recording device, such as disclosed

1 in U.S. Patent No. 5,771,310 to Vannah, or by using other known marking techniques.  
2 Although numerous points may be taken, ideally a minimum number of points are taken  
3 to define accurately the target articular surface. In other embodiments, multiple  
4 outriggers that embody different diameters or an adjustable outrigger may be used to map  
5 larger defects, and also to determine the final diameter of the prosthetic surface that fits  
6 within the defect. It is noted that the measuring tool may comprise a spring or other  
7 tensioning device (not shown), for urging the outrigger distally with respect to the handle  
8 of the tool. In this aspect, the outrigger is manually pressed against the articular cartilage,  
9 so as to maximally compress the articular cartilage upon recording data points, so that the  
10 data points taken are of a maximally "loaded" or "compressed" dimension.

11 FIGS. 20a, 20b and 20c show an alternative measuring and mapping device 210  
12 for obtaining the articular surface dimension, comprising housing 217 and a recording  
13 element 218. As shown in FIG. 20a, recording element 218 includes upper portion 219,  
14 flange 222 and calibrated lower portion 220. Key-shaped surface 221 located at distal  
15 end 225 of recording element 218 is configured to engage a reciprocal key-shaped  
16 surface in the proximal extension 14 of fixation screw 10, or, for example, a key shaped  
17 cover arranged on the proximal end of the screw (not shown). The upper portion 219 of  
18 recording element 218 may be constructed of a relatively soft or other deformable  
19 material that can be marked with patient data. Cannulated shaft 223 runs through the  
20 central lumen of the recording element 218. As shown in FIG, 20b, housing 217  
21 includes a marking mechanism 224 located on the upper portion 226 of the housing, at or  
22 within window or aperture 230. An indexing indicator 228 is located on the lower  
23 portion 227 of the housing 217, at window or opening 229.

24 Turning to FIG. 20c, recording element 218 is inserted in housing 217 of  
25 measuring and mapping device 210, so that the distal end 225 of recording element 218  
26 appears through opening 232. Tensioning means (not shown) in the device 210, enables  
27 recording element 218 to move longitudinally within housing 218. With the guide pin 20  
28 replaced, the measuring device 210 is inserted on the guide pin on reference axis 20A so  
29 that key-shaped surface 221 engages the corresponding keyed surface of the screw and is

1 maintained in static position thereby. These key-shaped surfaces establish the rotational  
2 position of the articular surface points to be mapped relative to the screw. During the  
3 measuring and mapping procedure, the surgeon rotates housing 217 and outer arm or  
4 outrigger 231 located at the distal end 235 of housing. By depressing marking  
5 mechanism 224, a series of depressions or marked points 240 is established in the  
6 relatively soft surface of the upper portion 219 of the recording element 218, which  
7 deforms at these marked points so that they can be utilized as patient data. Indexing  
8 indicator 228 and calibrated lower portion 220 of recording element 217 allow for  
9 controlled rotational movement between housing 217 and recording element 218. In  
10 this way, the rotational position of the mapped articular surface points 235 relative to the  
11 screw 10 as appreciated by outer arm of outrigger 231, is translated to the implant  
12 geometry as a feature so that the accurate rotational location of the implant 40 relative to  
13 the screw 10 is maintained.

14 For example, as shown in FIGS. 8b and 9b, to accurately reproduce the two radii  
15 60 and 61 that locally define the articular surface 55, four points, 81a and 81b, and 82a  
16 and 82b, and the point of origin 80 are recorded. As any three points in a single plane  
17 define a curve, by recording points 81a and 81b and the point of origin 80, radius 60  
18 defining the medial-lateral aspect 68 of the chondyle can be determined. By recording  
19 points 82a and 82b and the point of origin 80, the radius 61 defining the anterior-posterior  
20 aspect 69 of the chondyle can be determined. In the example provided, in order to  
21 maintain the relationship between these two defined radii, 60 and 61, the measuring tool  
22 70 is constructed so that it can be accurately indexed from a fixed starting point along 90  
23 degree intervals to capture or map said four points 81a, 81b, 82a and 82b, over the course  
24 of its revolution.

25 Locating surfaces or features created on the radius cover 30, or along some length  
26 of the fixation screw 10, hex-shaped drive surface of the screw 14 or on the cylindrical  
27 proximal extension (or recess) of the screw 14, correlate to some surface or feature on the  
28 measuring tool 70 and allow the measurement of the rotational position of the four  
29 measured points 81a, 81b, 82 and 82b, about the reference axis 20A with respect to said



1 locating surfaces. This data becomes important in configuring the implant 40 with respect  
2 to the fixation screw 10 so that the proper orientation of said measured points to  
3 fabricated geometry is maintained. Of course, such measuring tool can be configured to  
4 measure any number of points at any interval desired.

5 While the measurements are illustrated in FIGS. 9a and 9b as being taken from  
6 the bottom of the radiused surface 31 of the hex-shaped cover 30 of the screw, the  
7 measurements may alternatively be taken from the top of the screw 10' itself, as shown in  
8 FIG. 9c. As shown, in this embodiment, a key 315 or other alignment feature may be  
9 provided, to indicate the starting point for taking measurements. In this configuration,  
10 the measuring tool used, as well as the implant manufactured, both have a mating feature  
11 matching the key 315, for properly locating the starting point of the measurements taken  
12 and thereby subsequently properly aligning the implant with respect to the defect.

13 Other embodiments of measuring and recording tools are possible. One such  
14 embodiment of a measuring and recording tool 210' is shown in FIGS. 20d – 20i. As  
15 shown, measuring tool 210' comprises a handle 316, outer shaft 333, inner shaft 330,  
16 scroll 317, a tactile feedback portion 318, ring 320 having a button 321 in communication  
17 with a sharp marking point 326 thereunder, a rotating portion 322 having a rotational lock  
18 323 which prevents rotation of the rotating portion 322 when engaged, and an outrigger  
19 portion 324. The handle 316 remains fixed during rotation and does not move while the  
20 tool 210' is used for measuring. Instead, the rotating portion 322 is rotated to a start  
21 position and the rotational lock is engaged, securing the rotating portion 322 to the tactile  
22 feedback portion 318 and thereby preventing its rotation. The scroll 317 is configured  
23 with a notch 325 or similar mating feature to align with a corresponding mating feature  
24 (not shown) of the handle 316, such that the scroll can only align at one rotational point,  
25 at 0 degrees, with respect to the handle 316 upon loading into the tool 210', e.g., by  
26 “snapping” into place. The sharp marking point 326 located inside the ring 320 under the  
27 sharp marking point 326, marks a point of depression into the scroll 317 while first button  
28 321 is being depressed. Instead of marking by making depressions on a scroll or spool,

1 marking could alternatively be made upon nearly any surface, e.g., using ink to record on  
2 a paper spool, or by digital means.

3 As shown in FIGS. 20f and 20g, outer shaft 333, which is fixedly coupled to  
4 rotating portion 322, outrigger 324 and ring 320, is freely rotatably disposed about inner  
5 shaft 330 and slidably disposed about inner shaft 330 within a range bounded by points  
6 334 and 337. In FIG. 20f, the outrigger 324 is retracted, and outer shaft 333 is located at  
7 a position of origin along a z-axis parallel to the inner 330 and outer 333 shafts, such that  
8 the proximal end of the ring 320 is located at position 335. In FIG. 20g, the outrigger  
9 324 is extended, and outer shaft 333 is located at a position .250 in. (.64 cm.) from the  
10 origin of the z-axis parallel to the inner 330 and outer 333 shafts, such that the proximal  
11 end of the ring 320 is located at position 335'. The motion of the sliding of the outer  
12 shaft 333 about inner shaft 330 during marking is translated via the outer shaft 333,  
13 rotating portion 322 and ring 320 (including marking button 321 and marking point 326)  
14 to a location along the scroll 317. Thus, as the user rotates outrigger 324 by rotation of  
15 rotating portion 322, the outrigger moves along the articular surface proximally or  
16 distally with respect to the inner shaft, and the displacement of the outrigger 324 along a  
17 z-axis parallel to the inner 330 and outer 333 shafts may be marked on the scroll 317 by  
18 depression of the button 323 at various points along the rotation of the outrigger 324.  
19 The tactile feedback portion 318 has a series of depressions 319 or other tactile feedback  
20 means, e.g. spring ball plungers which engage in indentations (not shown) in the inner  
21 shaft 330, spaced at 90 degrees from one another, so that when the rotational lock 323 is  
22 engaged as rotating portion 322 is being rotated, the user feels a "click" or other tactile  
23 feedback to indicate to the user the rotational location of the rotating portion 322 at 90  
24 degree intervals with respect to the handle 316, i.e., at 90 degrees, 180 degrees, 270  
25 degrees, and 0 (or 360) degrees, for purposes of marking at those points. It is further  
26 noted that the starting point for marking may or may not be selected independent of the  
27 90-degree rotational points, and that the rotating portion 322 may or may not be  
28 configured so that it is not tied to the 90-degree indexing until the scroll lock 323 is  
29 engaged.

1           As shown in FIGS. 20e, 20h and 20i, a keyed mating feature 331 may be disposed  
2   at the distal end of the inner shaft 330 with respect to the outrigger portion, for mating  
3   with a key feature 315 on the screw 10' (as shown in FIGS. 9c and 20i), so as to locate  
4   properly the starting point of the measurements taken with respect to the screw, and the  
5   scroll 317. FIG. 20h illustrates a more detailed view of the distal end of the marking tool  
6   210', with outer shaft 333, inner shaft 330 with keyed mating feature 331, and outrigger  
7   324 with rounded end 338, which travels along the path of circle 339. FIG. 20i illustrates  
8   the measuring tool 210', with the keyed mating feature 331 inserted into the recessed  
9   portion 303 of the screw 10' at its fixation element 302.

10           Referring now to FIG. 14a, data recorded during the mapping procedure described  
11   above can then be entered into a known parametric engineering design software or  
12   similar algorithm, as four values, 85a, 85b, 85c, and 85d, corresponding to the four  
13   measured points, 81a, 81b, 82a and 82b, with the origin 80 defining a reference plane.  
14   These four values 85a, 85b, 85c and 85d, are represented by line elements that are  
15   geometrically constrained to lie upon a circle 90, which represents the diameter of the  
16   measuring tool 70. These line elements are also constrained to lie within planes that are  
17   perpendicular to one another. Of course, more than four points may be taken and used to  
18   map the articular surface, e.g., 8 points; however, a minimum of four points should be  
19   taken, so that two intersecting datum curves may be defined for purposes of mapping.

20           Datum curves 86 and 87, representing the medial-lateral ("ML") and anterior-  
21   posterior ("AP") curves, are constructed by connecting the end points of the line elements  
22   81a and 81b, and 82a and 82b and the point of origin 80, which is common to both  
23   curves. These two datum curves 86 and 87 can be used to construct the articular or  
24   bottom surface 41 of the prosthetic implant 40. By sweeping datum curve 87 along a  
25   path defined by datum curve 86, a three dimensional surface is now defined.

26           By constructing this series of geometric relationships in a known parametric  
27   engineering model, patient-specific geometry can be input as values and the model  
28   algorithm can be run to reproduce the anatomic contours mapped in the patients within  
29   only a few moments. As a process, this generic model is the starting point for all patient

1 treatments. Sterile pins, screws, and measuring devices that are all non-patient-specific  
2 may be stocked in the hospital and ready to use whenever an appropriate defect is  
3 diagnosed. Patient-specific data may be transmitted from the surgeon to the fabricating  
4 facility via an interface to the Internet or other network. Data input into the interface may  
5 be read directly into the generic parametric model to produce a viewable and even  
6 mappable patient-specific parametric model within moments. Confirmation by the  
7 surgeon could initiate a work order for the production of the patient specific device.  
8 Existing technology allows the parametric model to generate toolpaths and programming,  
9 e.g., to a CAD/CAM system comprising appropriate hardware and/or software coupled to  
10 appropriate data-driven tools, to fabricate the implant.

11         Defining two additional datum curves 88 and 89, at offset distances from datum  
12 curves 86 and 87, is performed to define the top or non-bearing surface 42 of the implant  
13 40. This top surface 42 should be closely matched to the bearing surface geometry to be  
14 implanted without having to remove an excessive quantity of bone from the chondral  
15 surface.

16         Referring to FIGS. 14c and 19c, implant geometry may be defined whereby the  
17 top or bone contacting surface 42 of the implant 40 exhibits an axial symmetry. The  
18 central axis AA passes through the point of origin 80 of the implant 40 and when the  
19 implant is positioned at the target site, aligns with the original reference axis 20A as  
20 defined by the guide pin 20 and fixation screw 10. The central axis AA can then be used  
21 to define the preparation tools so that the bone contacting surfaces 42 of the implant 40  
22 and the preparation tools can be matched in both configuration and dimension to create a  
23 mating fit between the surface of the prepared target site and the bone contacting surfaces  
24 42 of the implant. For example, if the preparation tools can be fabricated using some of  
25 the same dimensions obtained during the articular surface mapping procedure, the  
26 implant geometry and corresponding preparation tool geometry can be mated and  
27 optimized so that a minimum vertical thickness of the implant as well as a minimum  
28 depth of bone removal is required. This may be advantageous in ensuring good long  
29 term clinical results with the implant, as poor quality of fit between bone surfaces and

1 bone-contacting surfaces of traditional orthopedic prosthetic devices has been noted to  
2 contribute to early clinical failures.

3 For example, as shown in FIGS 14c and 19c the top or bone contacting surface 42  
4 of the implant 40, a series of radial cuts 198 may create surfaces that increase resistance  
5 of the implant to rotational forces. These features may be located at the outer diameter  
6 190 of the implant 40 to increase their effectiveness. Additional contact surfaces may  
7 also be created by one or more protrusions 195 located on the bottom 42 of the implant.  
8 Similarly, surface treatments known in the field of orthopedic devices, such as porous  
9 and/or osteoconductive coatings, may be utilized on surface 42.

10 As shown in FIG. 19b, outer diameter 190 may include a slight outward taper or  
11 protrusion 197 along the diametrical surface to enhance load bearing or load transfer  
12 properties of the implant to surrounding bone. This feature may also increase the fixation  
13 strength of the implant. A fillet 199 (as shown in FIG. 19a) that runs around the implant  
14 at the intersection of the diametrical surface 190 and the bearing surface 41 is also useful  
15 in providing a smooth transition between the host articular cartilage and the implant  
16 surface.

17 However, if a greater depth of implant is needed as a result of the defect  
18 appearance the offset curves 88 and 89 (as shown in FIG. 14a) can be extended to  
19 increase the overall thickness of the implant 40 or the offset curves may be eliminated  
20 entirely so that the contoured surface is backed by a revolved geometry that is  
21 symmetrical to reference axis 20A. Turning to FIG. 19c, where the ML curve and AP  
22 curve (defined by the obtained measurements) are not axially symmetrical, the thickness  
23 of the implant 40 requires adjustment. At the same time, an unnecessarily thick implant  
24 requires a greater amount of bone to be removed at the target site. Therefore, the  
25 thickness of the implant may be determined by taking the largest obtained measurement  
26 and adding a minimal offset amount 208. (The implant is thinnest at the highest point on  
27 the ML curve.) This can be similarly accomplished by adjusting the angle  $\Delta$  (FIG. 19a)  
28 of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the  
29 preparation tool. This also allows for a correction of the implant geometry, to

1   compensate for any non-perpendicular placement of the guide pin with respect to the  
2   articular surface.

3           With reference now to FIGS. 25 and 26, an exemplary algorithm consistent with  
4   the invention establishes the minimum thickness of an implant necessary to include all  
5   patient data points, receiving as input all of the points measured (typically, four) and  
6   identifying the largest value. One such exemplary algorithm is as follows (and as shown  
7   in FIGS. 25 and 26):

```
8           maxval= D6
9           if maxval < D11
10               maxval = D11
11           endif
12           if maxval < D14
13               maxval = D14
14           endif
15           D684 = maxval + .045
```

16

17   In the foregoing exemplary algorithm, a first data point D6 is initially assigned as the  
18   maximum value (maxval). If...then type statements are used to compare other data  
19   points (D11 and D14) to maxval. If other data points are greater than maxval, the  
20   algorithm reassigns maxval to the new larger data point. LLMT represents the height of  
21   the lower limit plane along the z-axis, and ULMT represents the height of the upper limit  
22   plane along the z-axis. D684 is a dimension that controls the ULMT plane, which is  
23   established in the model as the upper surface of the implant. ULMT is positioned as  
24   maxval plus an additional arbitrary and/or fixed material offset (.045 in this case).

25           FIGS. 5c and 5d illustrate an alternative embodiment of the implant 40', having a  
26   ML curve between data points 340 and 341 and an AP curve between data points 342 and

1 343, with male-shaped mating component 304 and key-shaped portion 344 for  
2 engagement with a reciprocal key-shaped surface in the proximal extension of a fixation  
3 screw, protrusions 345 (creating contact surfaces on the top 346 of the implant 40'),  
4 radial cuts 347 located at the outer diameter 348 of the implant 40', and radius 349  
5 (which may be formed, e.g. using an abrasive wheel) around the intersection of the outer  
6 diameter at point 341 and the surface comprising the patient geometry.

7 Referring to FIGS. 18a and 18b, bone cutting or scoring instrument 250 includes a  
8 handle (not shown), a cannulated shaft 111 that extends through the handle, and offset  
9 arm 140 housing adjustable blades 141. In the embodiment shown, individual cutting  
10 blades 141 are attached to offset arm 140 either fixedly or removably, e.g. via threaded  
11 portions 142, into threaded recesses 342 of the offset arm 140, although other attachment  
12 means may be used. With guide pin 20 advanced through shaft 113 positioned on the  
13 reference axis 20A, a fixed distance from the rotational or references axis 20A to each of  
14 the cutting or scoring blades 141 is established. These lengths define the radii that are  
15 to be effected in the articular surface, as the scoring instrument 250 is rotated around the  
16 guide pin 20, corresponding to the protrusions 195 on the bone contacting surface 42 of  
17 the implant 40 creating a matching fit between the bone surfaces of the prepared target  
18 site and the bone contacting surfaces of the implant.

19 In an alternative embodiment, as shown in FIG. 18c, cutting blades are arranged  
20 on carrier 145, configured so that it can be mounted within the slotted surface 114 of  
21 offset arm 112, depicted in FIG. 17a. In another embodiment, as shown in FIG. 18d,  
22 cutting blades 141 can be fixedly positioned on offset arm 140. Using the same  
23 dimensions obtained during articular surface mapping procedure, the cutting and scoring  
24 device 250 can be fabricated to prepare the articular surface to correspond to the implant  
25 geometry to optimize fit. In another alternative embodiment, as shown in FIG. 18e, a  
26 bone cutting instrument 352 corresponds to the alternative embodiment of the implant 40'  
27 illustrated in FIGS. 5c and 5d. Instrument 352 has a handle (not shown), a cannulated  
28 shaft 353 that extends through the handle and through the cannulation 355, offset arm  
29 354 with blades 350 and 351 corresponding to the protrusions 345 on the bone contacting

1 surface 42 of the implant 40 creating a matching fit between the bone surfaces of the  
2 prepared target site and the bone contacting surfaces 346 of the implant 40'.

3 As shown in FIG. 14b, an angular dimension 95, relating some locating surface or  
4 feature on the hex-shaped cover 30 or on the fixation screw 10, to the four points 81a,  
5 81b, 82a and 82b, may also be captured at the time of the initial procedure to assist in  
6 orientation of the implant 40 to the fixation screw 10. Guide aperture 46 in implant 40 is  
7 located off the reference axis 20A and may serve as the locating feature and/or as a suture  
8 passage way in the implantation procedure. Alternatively, a surface or feature created on  
9 the implant 40, may serve to reference or align to such locating surface on the hex-shaped  
10 cover 30 or the fixation screw 10.

11 Additional data can be taken at the time of the initial procedure, e.g., for  
12 fabricating a non-circular implant. Additional data curves can also be defined by  
13 measuring the offsets from the reference axis 20A and determining diameters at these  
14 offsets. The final implant geometry, although measured using circular techniques, need  
15 not be circular.

16 Referring to FIGS. 10a and 10b, following fabrication of the implant 40, a second  
17 procedure is performed. If a cover 30 (or plug) is in place, it is removed, exposing  
18 proximal extension 14 (or recess) or some other precision taper or engagement surface  
19 located at the proximal end 17 of the fixation screw 10 to which the implant 40 is to be  
20 affixed. A pin having a distally mounted element or barb 5 is placed through through  
21 hole 16 running through the central lumen of the fixation screw 10 so that the distally  
22 mounted element 5 is secured into the screw. The distally mounted element 5 carries one  
23 or more suture strands 85 that now trail from the fixation screw 10. Alternatively, a pin,  
24 braided cable, or flexible wire may also be used. However, sutures may make passing the  
25 implant 40 through the incision 200 and subsequent handling easier.

26 Turning to FIGS. 11a and 11b, the sutures 85 are then threaded through guide  
27 aperture 46 of the implant 40 and a knot or bead 49 may be created proximal to the  
28 implant, so that tensing one of the free running sutures 85 helps to advance the implant



1 40 toward the proximal extension 14 (or recess) of the fixation screw 10. Alternatively,  
2 the suture strands 85 can be passed through the central lumen or shaft of a driving rod or  
3 other instrument to aid in seating the implant 40, and positioned in the fixation screw 10  
4 thereafter.

5 If necessary, the arthroscopic wound 200 is expanded slightly in either a vertical  
6 or horizontal direction, so that the implant 40 may be passed through. A polymeric  
7 sleeve (not shown) positioned over the implant may prove helpful in passing the implant  
8 through the incision. As shown in FIG. 11b, based on the size of the implant 40,  
9 anatomy of the knee 50, and retraction of the knee, it may be necessary to position the  
10 implant in the interchondular notch 77 as a staging area prior to final placement. By  
11 continuing to manipulate and tension the suture strands 85, the implant 40 can be brought  
12 coaxial to the proximal extension 14 of the fixation screw 10.

13 As shown in FIGS. 15c and 15d, alternatively, driver 130 includes handle 110, a  
14 cannulated shaft 111 that extends through the handle and a cannulated seat portion 131  
15 attached to the end of the shaft. Tether element 135, which may comprise sutures or  
16 wire, is passed through driver 130 and is threaded through implant 40 through guide  
17 aperture 46, connecting the implant to the driver toward seat portion 131. The implant  
18 40 and the driver 130 are then inserted arthroscopically through incision 200 to the target  
19 site. By tensioning tether element 135 at the end 136 of handle 110, the implant 40 is  
20 drawn back into seat portion 131 of driver 130. By maintaining tension on tether element  
21 135, the implant 40 can then be controllably delivered to the prepared target site. At  
22 least the inner surface of seat portion 131 comprises a material that can be impacted to  
23 seat the implant 40 without damaging the implant surface.

24 Referring to FIG. 12, once coaxial, the implant 40 can be aligned via engagement  
25 of the proximal extension 14 on fixation screw 10 and precisions taper 44 on the bottom  
26 surface 42 of the implant and any locating feature, and driven into place with a plastic  
27 driving rod 91 and mallet 95. A protrusion 92 of high strength material mounted at the  
28 distal tip 93 of the driving rod 91 may be necessary to ensure that the rod stays centered  
29 on the implant 40 during driving.

1           Finally, as shown in FIG. 13, through guide aperture 46 on the upper surface 41 of  
2   the implant 40, bone cement 300 may be injected to enhance the contact surface between  
3   the implant 40 and the subchondral bone 100. Vents, such as milled slots 13 in the  
4   fixation screw 10, and in the walls of the implant central protrusion may be desirable to  
5   facilitate the flow of such materials.

          Alternatively, guide aperture 46 in the implant 40 may be altogether eliminated by  
using an alternative implant delivery system, as shown in FIGS. 19d through 19i,  
8   corresponding to an implant similar to that shown in FIGS. 5c and 5d. The alternative  
9   system comprises the implant 40'' and a washer 361 for holding a suture 363, the washer  
10   361 being adapted to fit into a taper lock ring 360. The ring 360 has a taper lock portion  
11   362 having a series of notches 365 along its perimeter, creating flaps 372 that permit the  
12   taper lock portion 362 to flex somewhat. The taper lock portion 362 has a diameter  
13   gradually tapering from the middle to the proximal end 364 of the ring. The taper lock  
14   ring 360 may also have an alignment notch 386 or similar feature for properly aligning  
15   the taper lock ring 360 with respect to key-shaped portion 344 of the implant 40'', which  
16   is to engage with a reciprocal key-shaped surface in the proximal extension of a fixation  
17   screw, so as to seat properly the implant rotationally with respect to the defect site when  
18   it is later seated thereon. A washer 361 is disposed between the ring 360 and the implant  
19   40'' and has two apertures 366 disposed in a recessed area 367 in the center of the  
20   washer. The suture 363 is threaded through the two apertures 366 to form a suture loop  
21   368, which remains in the recessed area when the ends of the suture 363 are pulled, so as  
22   to keep the suture loop 368 below the top surface 369 of the washer 361. The implant  
23   40'' has a diameter at its center portion 370 that is approximately equal to the inner  
24   diameter of the ring 360 at its taper lock portion 362. Thus, when tension is applied to  
25   the ends of the suture 363, the taper lock portion 362 of the ring 360 may flex outward to  
26   receive slidably therein the implant 40'' and washer 361, which subsequently lock into  
27   the taper lock portion 362 of the ring, once the center portion 370 of the sides of the  
28   implant 40'' is seated within the proximal end 364 of the ring by friction fit, as shown in  
29   FIG. 19e. It is noted that the center portion 370 of the sides of the implant 40'' to be of a

1 width permitting the implant and washer to travel slidably within the ring 360 to some  
2 degree.

3 As shown in FIG. 19f, a hex nut 373 may be integrally formed in the center of the  
4 washer 361 on its bottom side 374, for mating with an appropriately configured tool for  
5 seating the implant 40''. As FIG. 19f illustrates, the implant 40'', along with washer 361,  
6 ring 360, and sutures 363, is pushed through the incision 200 at the defect site. Next, as  
7 shown in FIGS. 19g – 19i, illustrative of successive steps in the process of seating the  
8 implant, a seating tool 380 may be used to seat the implant. Seating tool 380 comprises a  
9 shaft 385, a handle 381 (which may have a through hole 382, if the same handle and/or  
10 shaft is used with interchangeable tips for performing various functions, although a  
11 through hole 382 is not integral to seating the implant), and tip 383 suitably configured to  
12 drive hex nut 373 (or other mating feature) and having an aperture 384 through which the  
13 ends of the suture 363 may be threaded. Once the tip 383 of the tool 380 is introduced  
14 into the incision 200, the sutures 363 may be used as a guide for seating the tip 383 of the  
15 tool 380 onto the hex nut 373, which may be accomplished by alternately pulling on each  
16 end of the suture 363 to toggle the tip 383 of the tool 380 back and forth. Once the tip  
17 383 of the tool 380 is seated onto the hex nut 373, the tool 380 may be rotated in either  
18 direction to seat the implant assembly properly (comprising implant 40'', taper lock ring  
19 360, and washer 361) at the defect site. This may be effected by rotating tool 380 until  
20 alignment notch 386 and corresponding key-shaped portion 344 of the implant 40'' are  
21 aligned with the corresponding reciprocal key-shaped surface in the proximal extension  
22 of the fixation screw, whereby the implant should slide into place, thereby properly  
23 seating the implant rotationally with respect to the defect site. As shown in FIG. 12 with  
24 respect to the prior described embodiment, once properly seated, the implant 40'' can be  
25 driven into place with a plastic driving rod 91 and mallet 95, and as shown in FIG. 13  
26 with respect to the prior described embodiment, bone cement 300 may also be placed  
27 prior to the final seating of the implant 40'' to enhance the contact surface between the  
28 implant 40'' and the subchondral bone 100. It should be understood that the taper lock  
29 ring 360, washer 361, and sutures 363 described with respect to this embodiment allow

1 the implant to be noncannulated but still easily handled. These elements are not required  
2 to be constructed as illustrated herein, and may be replaced by adhesive components,  
3 suction components, or other components serving the same function.

4 As FIGS. 21 and 22 illustrate, a unitary (one-piece) implant 400 may also be  
5 constructed, thereby obviating the need for a fixation screw, taper lock ring, washer, and  
6 suture. In this embodiment, implant 400 has key-shaped portion 401 for engagement  
7 with a reciprocal key-shaped surface 411 in an aperture 412 at the defect site 410, a  
8 plurality of barbs 402 for producing outward tension within the aperture 412 at the defect  
9 site 410 and for increasing the contact surface area of the implant 400 with respect to the  
10 aperture 412 at the defect site 410. In this embodiment, an aperture 412 having a key-  
11 shaped surface 411 or other feature for mating with the implant is created directly in the  
12 defect site 410, by boring, abrasion, or other techniques for forming an appropriately  
13 shaped aperture in the chondral bone 410 for receiving an implant 400 having a  
14 corresponding key-shaped or other mating feature 401. It should also be recognized that,  
15 in this or other embodiments, the fixation screw could be replaced with a tensioned  
16 member attachment, e.g., anchored to the distal femoral cortex. Alternatively, the  
17 fixation screw could be configured as a guide wire, only to define the axis AA  
18 corresponding to an axis about the point of origin in the implant to be used (as shown in  
19 FIGS. 14c and 19c), but not to provide mechanical anchoring to or for the implant.

20 FIG. 23 illustrates other alternative embodiments for an implant consistent with  
21 the invention, showing a perspective view of the components of an exemplary composite  
22 implant, in one embodiment of the present invention. As shown, implant 500 comprises  
23 top 501 and bottom 502 portions. Top portion 501 has a bottom surface 503 which may  
24 be glued, welded, bonded, or otherwise attached to top surface 504 of bottom portion  
25 502, while bottom surface 505 of bottom portion 502 comprises the patient geometry and  
26 is the load-bearing surface of the implant, as set forth hereinabove. Top 504 and bottom  
27 505 surfaces of the bottom portion 502 may comprise, in whole or in part, bioengineered  
28 material, while top portion 501 may comprise a material such as titanium. In such a  
29 configuration, top portion 501 may be fabricated and/or manufactured (e.g. in large

1 quantities) as a universal, generic, standard supply item for medical practitioners, which  
2 merely needs to be attached to a custom-machined bottom portion 502 comprising the  
3 patient-specific geometry. Surfaces 503 and 504 may be flat or may comprise other  
4 mating features, shapes or configurations.

5 Further composite implant embodiments are illustrated in FIG. 24, wherein  
6 implant 600 comprises the patient-specific geometry 606 and a uniform thickness  
7 material bottom portion 602 comprising the bottom or bearing surface 606. The bottom  
8 surface 603 of top portion 601 mates with the top surface 604 of bottom portion 602, and  
9 surfaces 603 and 604 may be flat or may comprise other mating features, shapes or  
10 configurations. Lip 605 of bottom portion 602 has an inside diameter substantially the  
11 same as the outside diameter of top portion 601, so that top portion 601 fits slidably into  
12 bottom portion 602, whereby the two portions 601 and 602 may be glued, welded,  
13 bonded, or otherwise attached to one another. Bottom surface 606, being of uniform  
14 thickness, reflects the patient-specific geometry which surface 603 comprises and is the  
15 load-bearing surface of the implant.

16 Other materials from which an implant consistent with the invention may be  
17 constructed, in whole or in part, include ceramic, e.g. aluminum oxide or zirconium  
18 oxide; metal and metal alloys, e.g. Co-Cr-W-Ni, Co-Cr-M, CoCr alloys, CoCr  
19 Molybdenum alloys, Cr-Ni-Mn alloys, powder metal alloys, 316L stainless steel, Ti 6Al -  
20 4V ELI; polymers, e.g., polyurethane, polyethylene (wear resistant and cross-linked),  
21 thermoplastic elastomers; biomaterials, e.g. polycaprolactone; and diffusion hardened  
22 materials, e.g. Ti-13-13, Zirconium and Niobium. Coatings used may include, e.g.,  
23 porous coating systems on bone-contacting surfaces, hydrophilic coatings on load-  
24 bearing surfaces, hydroxyapatite coatings on bone-contacting surfaces, and tri-calcium  
25 phosphate on bone-contacting surfaces. Additionally, components of the invention may  
26 be molded or cast, hand-fabricated, or machined.

27 Alternatively, measurement methods may be utilized whereby radius  
28 measurements are taken with respect to an axis AA corresponding to an axis about the  
29 point of origin in the implant to be used (as shown in FIGS. 14c and 19c). The technique

1 is used in reverse, whereby aiming devices are used to place axis AA with respect to  
2 prefabricated generic-geometry implants.

3 It is noted that, although the invention is herein described as utilizing a single  
4 reference axis, multiple reference axes may be used for measuring, mapping, or cutting a  
5 single defect or an articular surface having multiple defects, as well as for fabricating a  
6 single implant, or multiple implants for a single articular surface, consistent with the  
7 invention. In other embodiments, methods for mapping the defect and/or articular  
8 surface other than those described hereinabove are possible, e.g., MRI or CT scanning.

9 It is further noted that, although the invention is described herein as utilizing the  
10 specific geometry of a patient's articular surface to fabricate an implant for that patient, it  
11 is contemplated that data from a plurality of patients may be analyzed statistically and  
12 utilized in fabricating and/or manufacturing (e.g. in large quantities) one or more  
13 universal, generic, or standard supply item type implants for medical practitioners to use  
14 in a procedure consistent with the invention. For such implants, as well as for patient-  
15 specific implants as described herein, pre- or post-implantation trimming may be required  
16 to correct for minor variations that may occur as between the implant and the subchondral  
17 bone (or other articular surface).

18 It should be understood that, although the various tools described hereinabove,  
19 e.g., for measuring, cutting, and seating, are described as separate devices, a single  
20 handle, shaft and/or instrument may be configured to serve as a universal mounting tool  
21 for a series of devices for performing various functions consistent with the invention.

22 Those skilled in the art will recognize that the present invention is subject to other  
23 modifications and/or alterations, all of which are deemed within the scope of the present  
24 invention, as defined in the hereinafter appended claims.

25

1           What is claimed is:

2           1.       A method for fabricating an implant for installation into an articular  
3 surface, said method comprising:

4                   mapping the contours of said articular surface; and  
5                   fabricating an implant based on said contours.

6           2.       A method as claimed in claim 1, wherein said mapping step further  
7 comprises:

8                   establishing a working axis with respect to said articular surface; and  
9                   recording, at a fixed or variable distance from said working axis, the  
10 location of a plurality of points along the articular surface with respect to said working  
11 axis.

12          3.       A fixation element for an implant for installation into an articular or bony  
13 surface, said fixation element comprising:

14                   a surface to engage said fixation element into an articular or bony surface;  
15                   and  
16                   a surface to engage said fixation element into an implant.

17          4.       A fixation element as claimed in claim 3, further comprising a rotational  
18 key for radial alignment with respect to said articular surface.

19          5.       A fixation element as claimed in claim 3, wherein said fixation element is  
20 a screw.

21          6.       A method for mapping the contours of an articular surface, said method  
22 comprising:

23                   establishing a working axis with respect to said articular surface; and  
24                   recording, at a fixed or variable distance from said working axis, the  
25 location of a plurality of points along the articular surface with respect to said working  
26 axis.

27          7.       A method for mapping the contours of an articular surface, said method  
28 comprising:

29                   establishing a working axis with respect to said articular surface; and

1                    recording the axial travel of an element contacting said articular surface as  
2       said element rotates about said working axis.

3            8.        A method as claimed in claim 7, wherein said recording step is performed  
4       by making one or more depressions into a spool coaxial with said working axis, whereby  
5       said axial travel of said element is translated to said spool.

6            9.        An implant for installation into an articular surface, said implant  
7       comprising:  
8            a bone-contacting or bone-facing surface; and  
9            a surface having a contour substantially matching or based on the contour of said  
10       articular surface.

11          10.       A method for determining the minimum thickness for an implant for  
12       installation into an articular surface, said method comprising:  
13            assigning a first data point as the maximum value;  
14            comparing said maximum value to other data points; and  
15            reassigning said maximum value for other data points that are greater than the  
16       existing maximum value.

17



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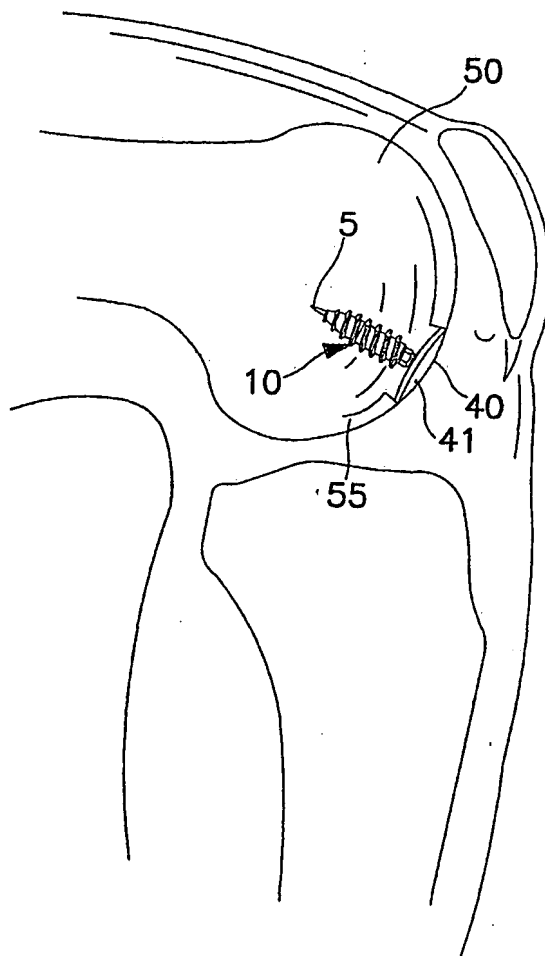


FIG. 1

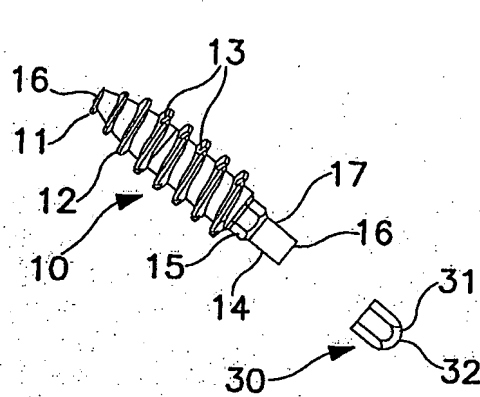


FIG. 2a

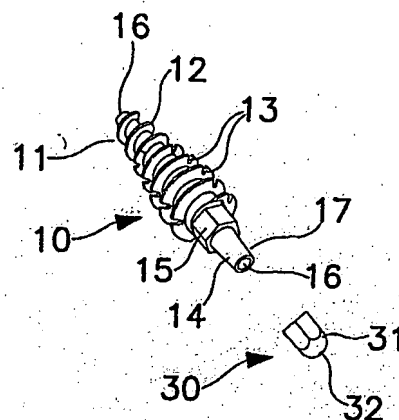


FIG. 2b

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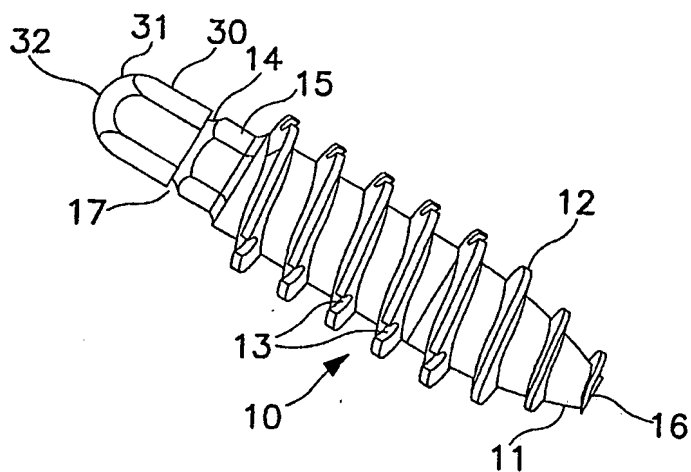


FIG. 3a

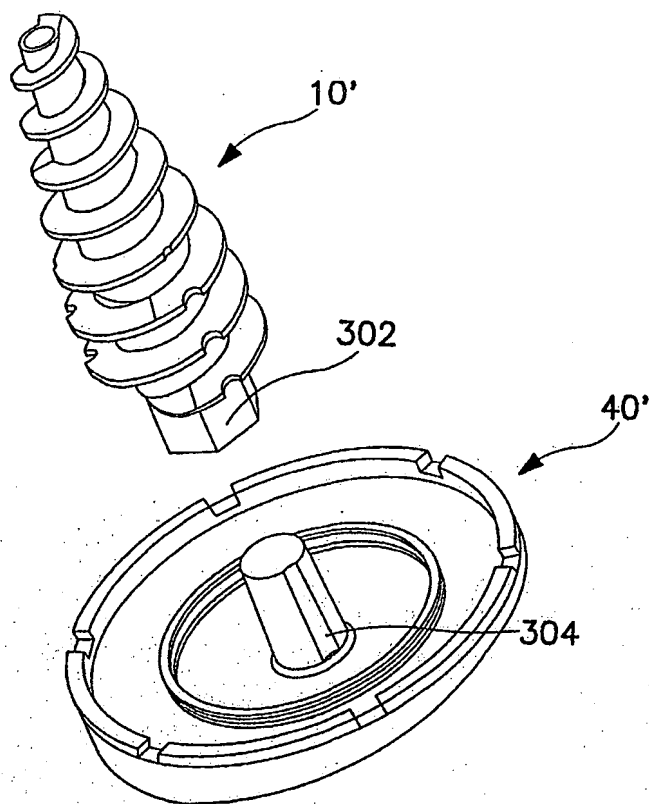


FIG. 3b

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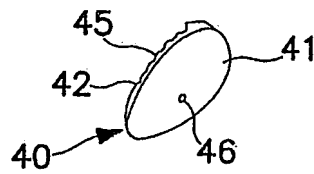


FIG. 4a

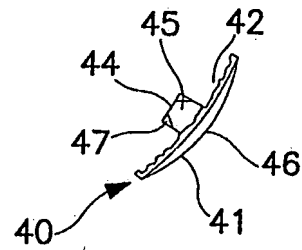


FIG. 4b

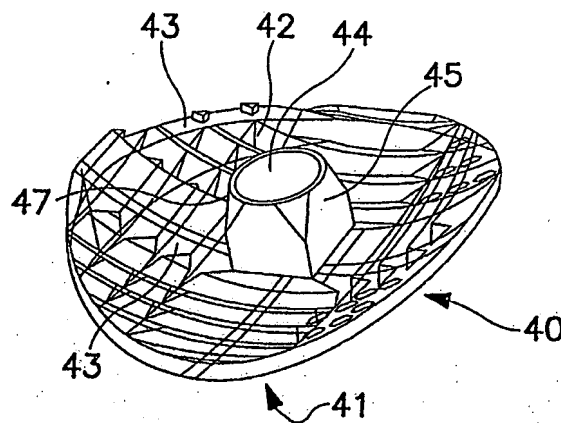


FIG. 4c

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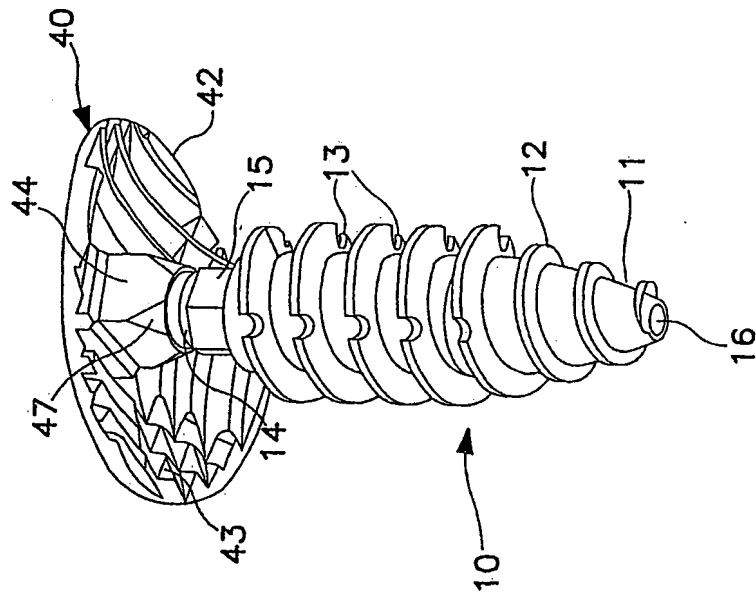


FIG. 5b

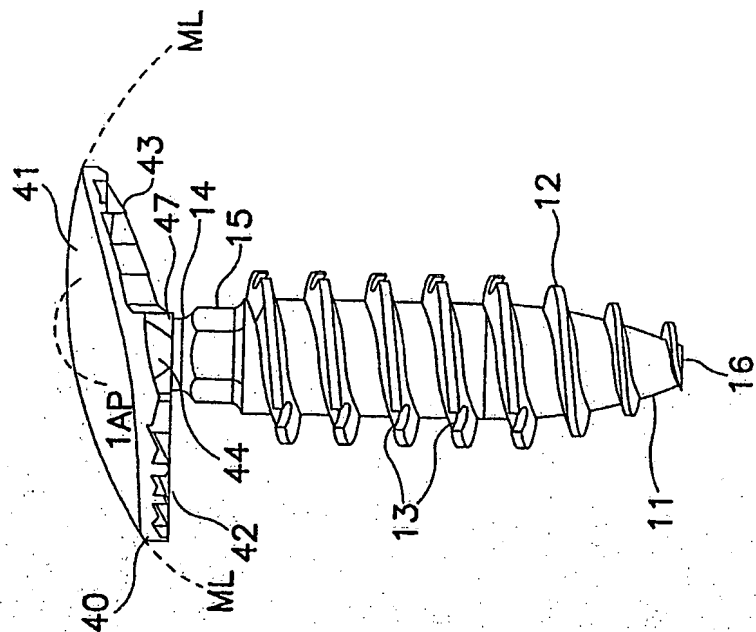


FIG. 5a

5 / 42

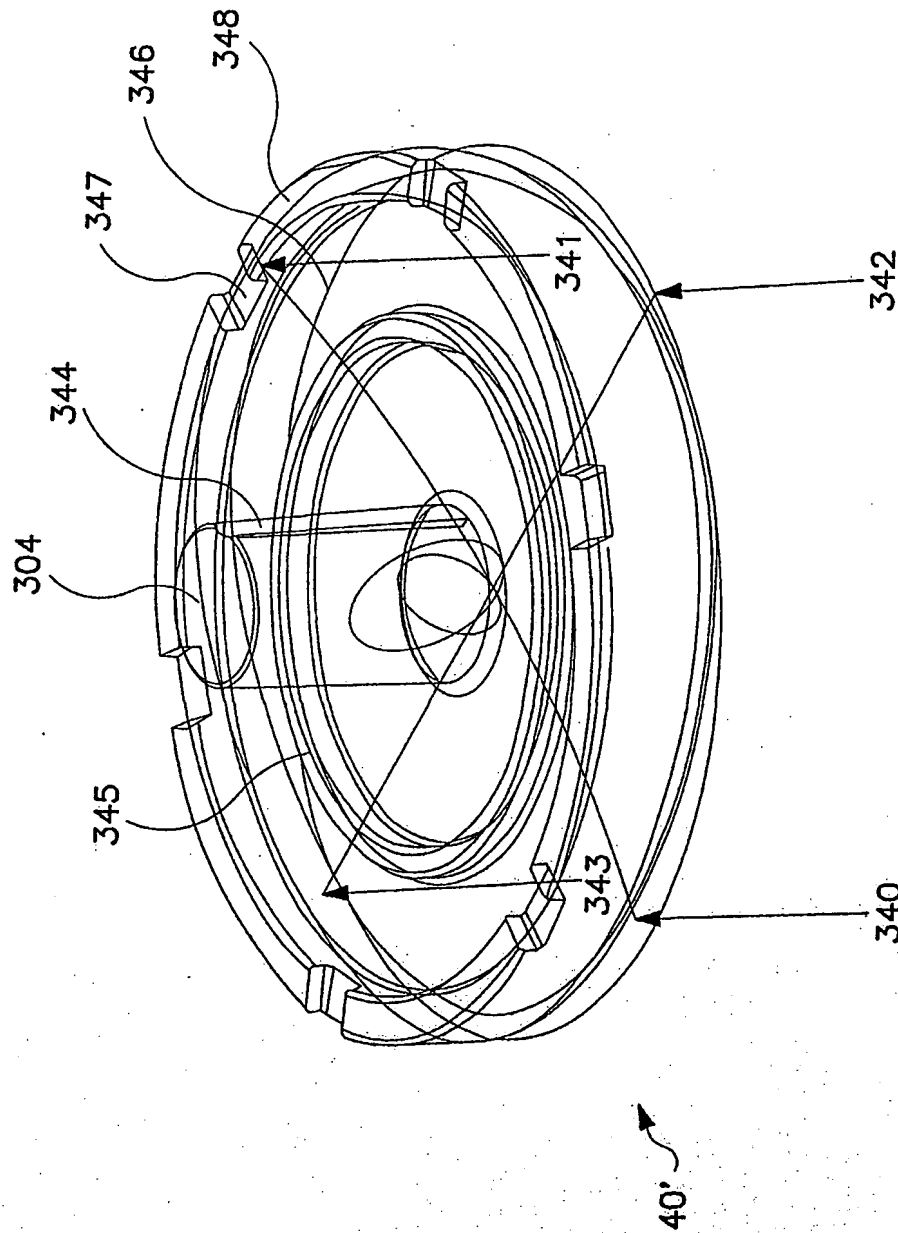


FIG. 5c

6 / 42

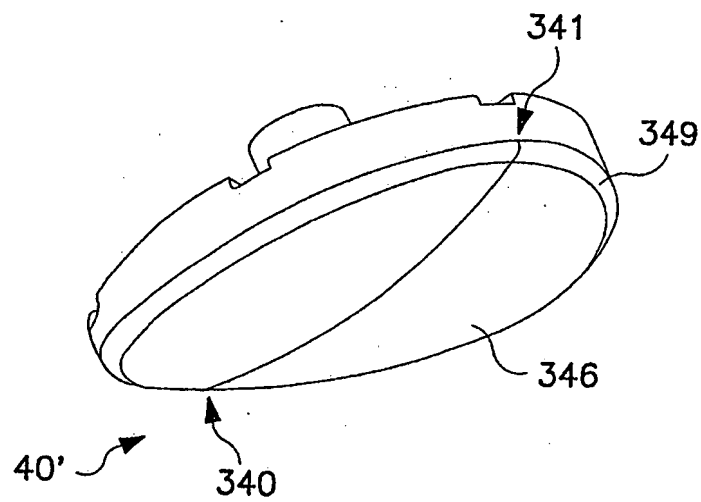
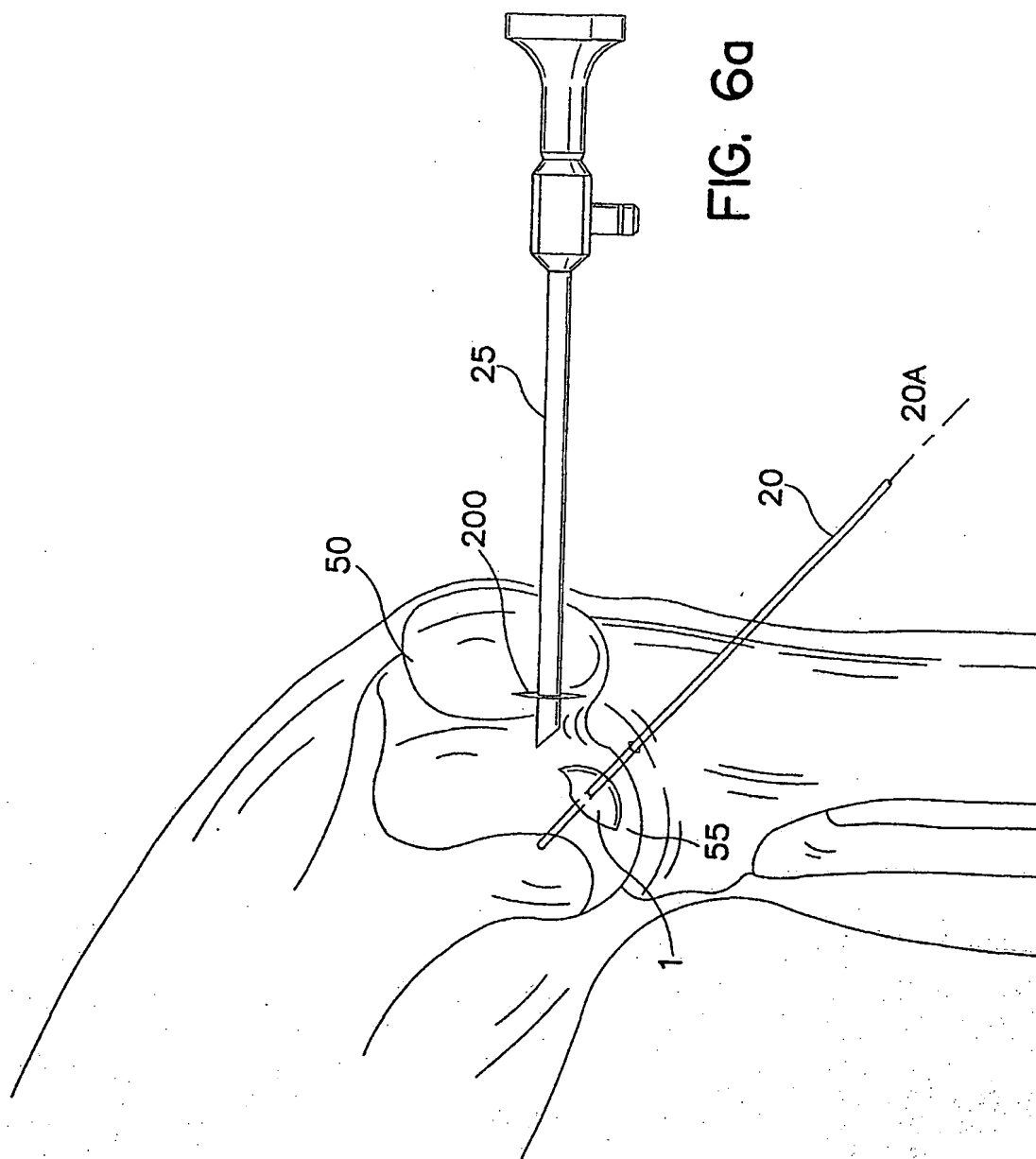


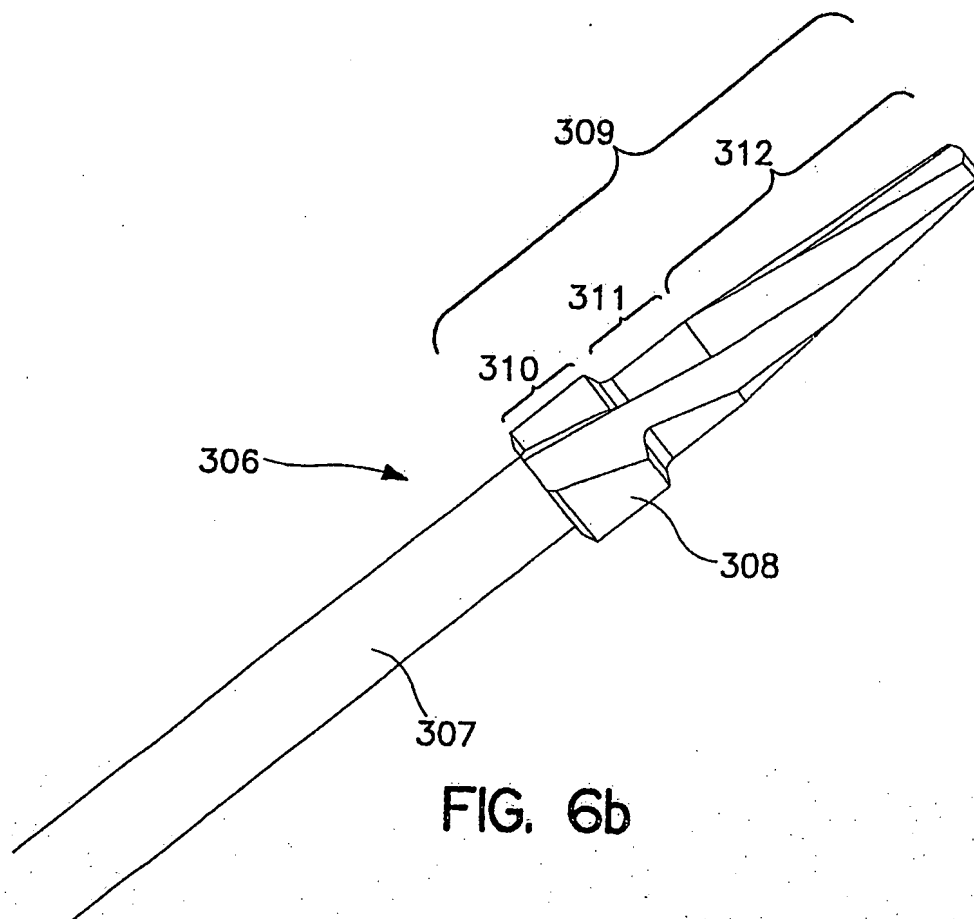
FIG. 5d

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SUBSTITUTE SHEET (RULE 26)

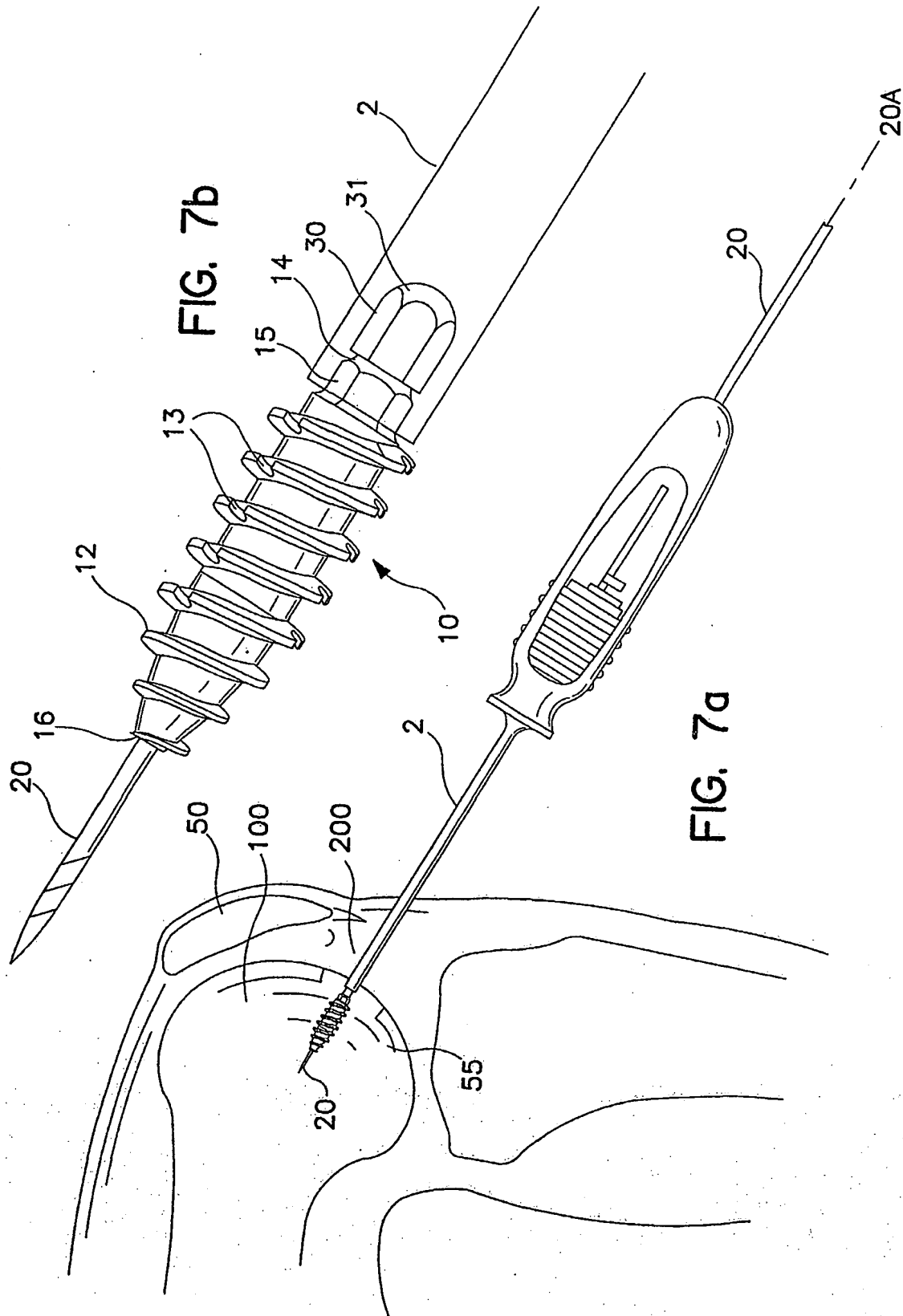
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SUBSTITUTE SHEET (RULE 26)

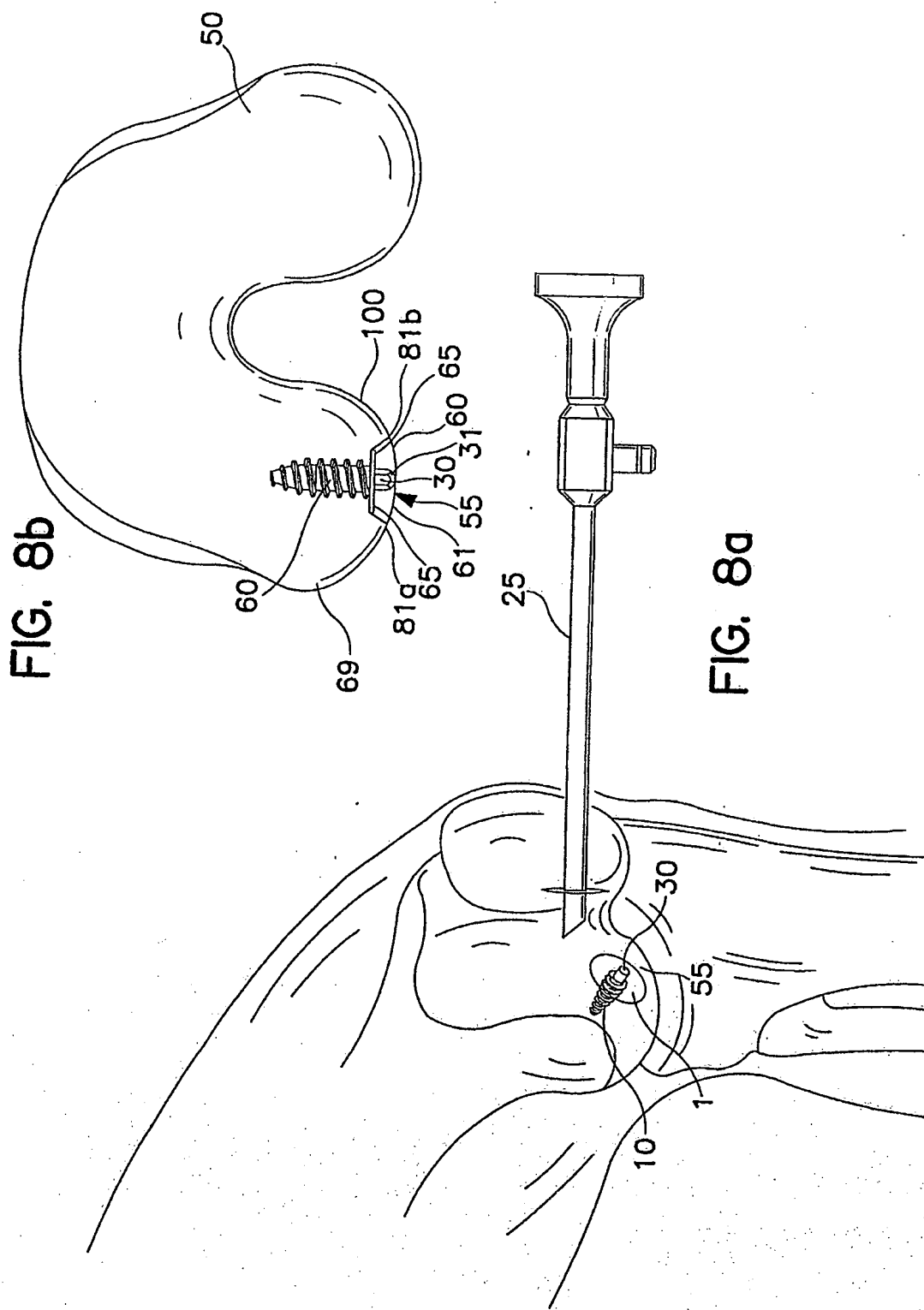


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**SUBSTITUTE SHEET (RULE 26)**

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SUBSTITUTE SHEET (RULE 26)

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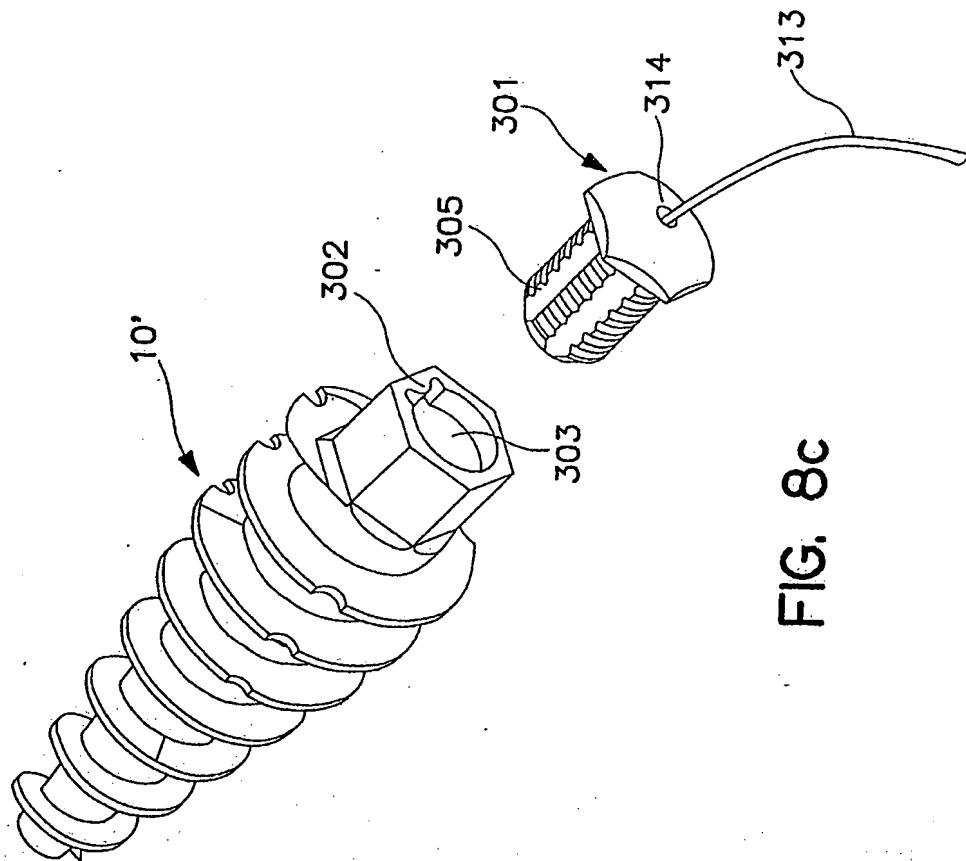
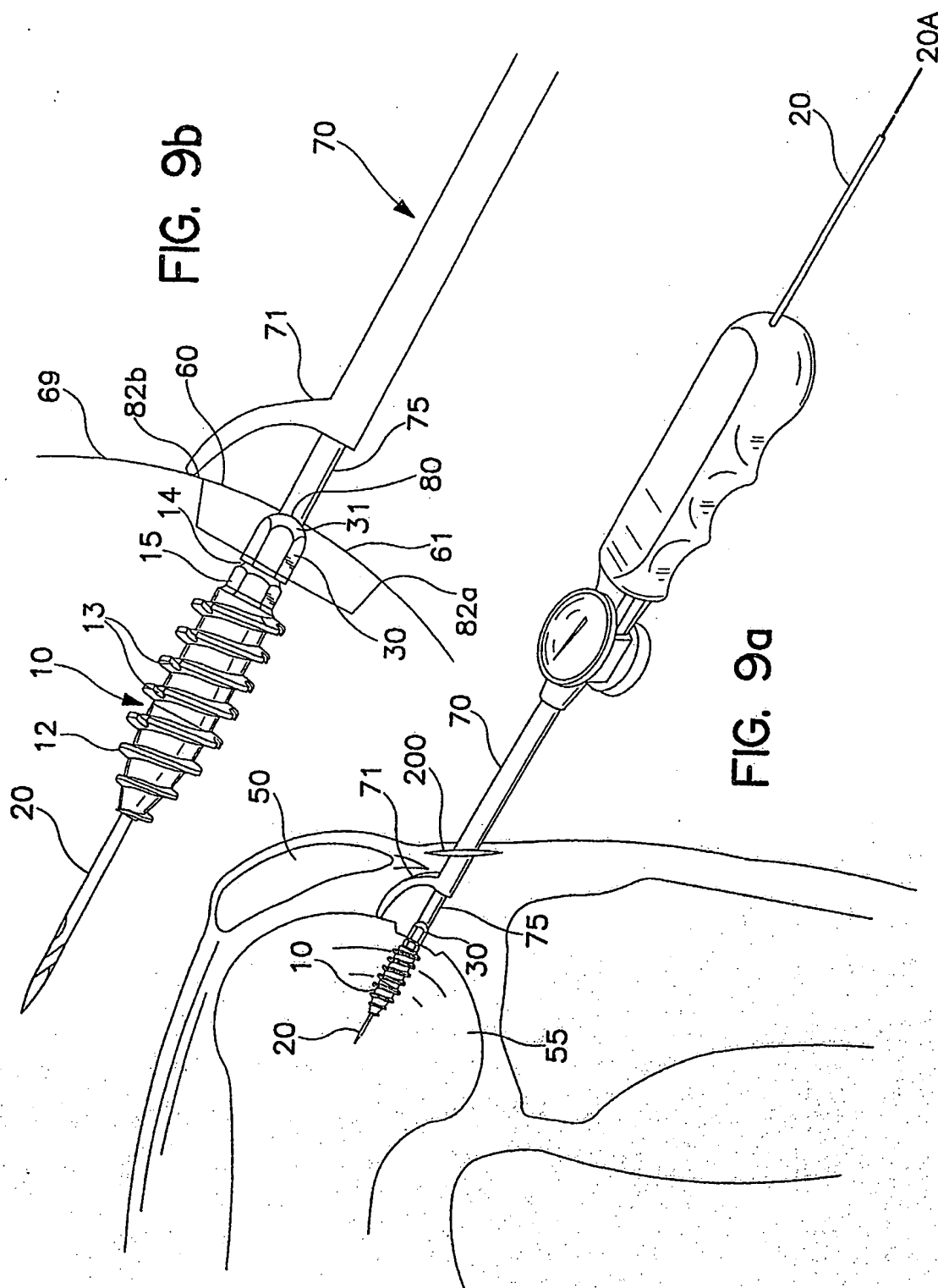


FIG. 8c

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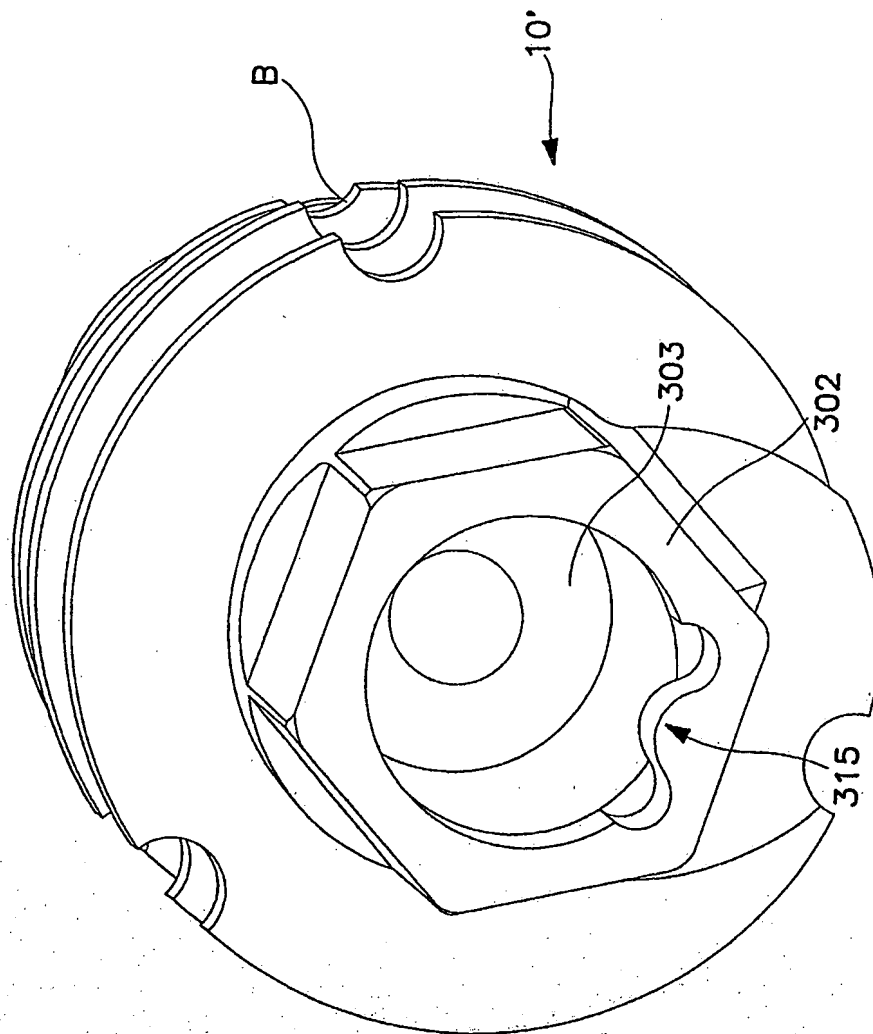
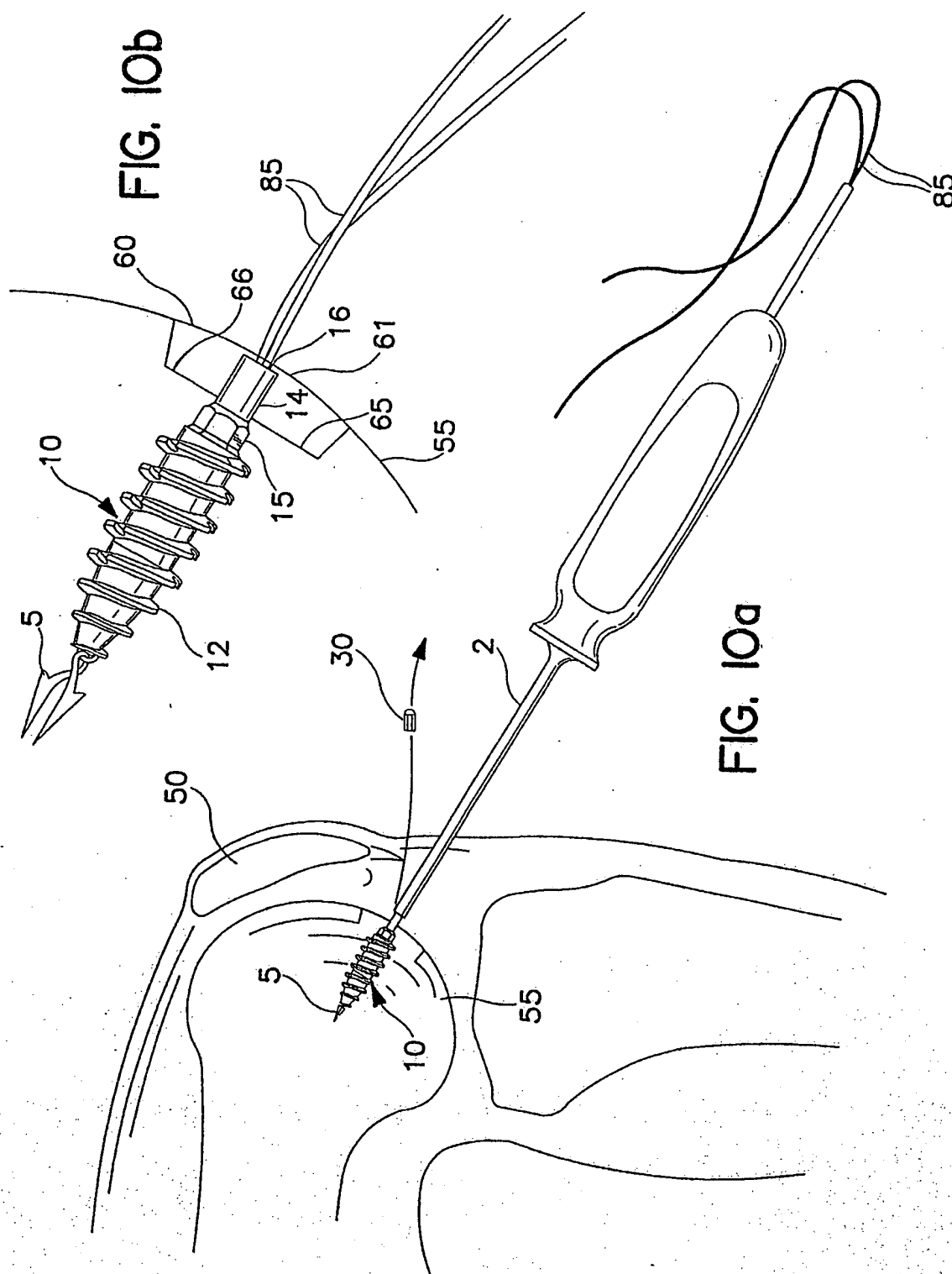


FIG. 9c



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FIG. 1 lb 15/42

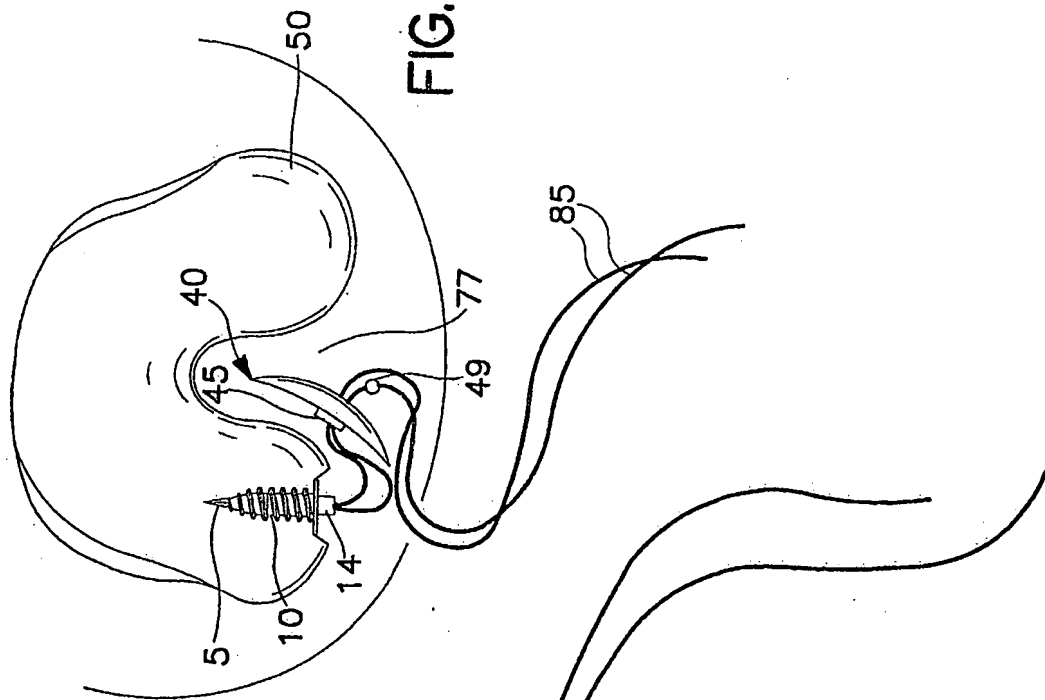
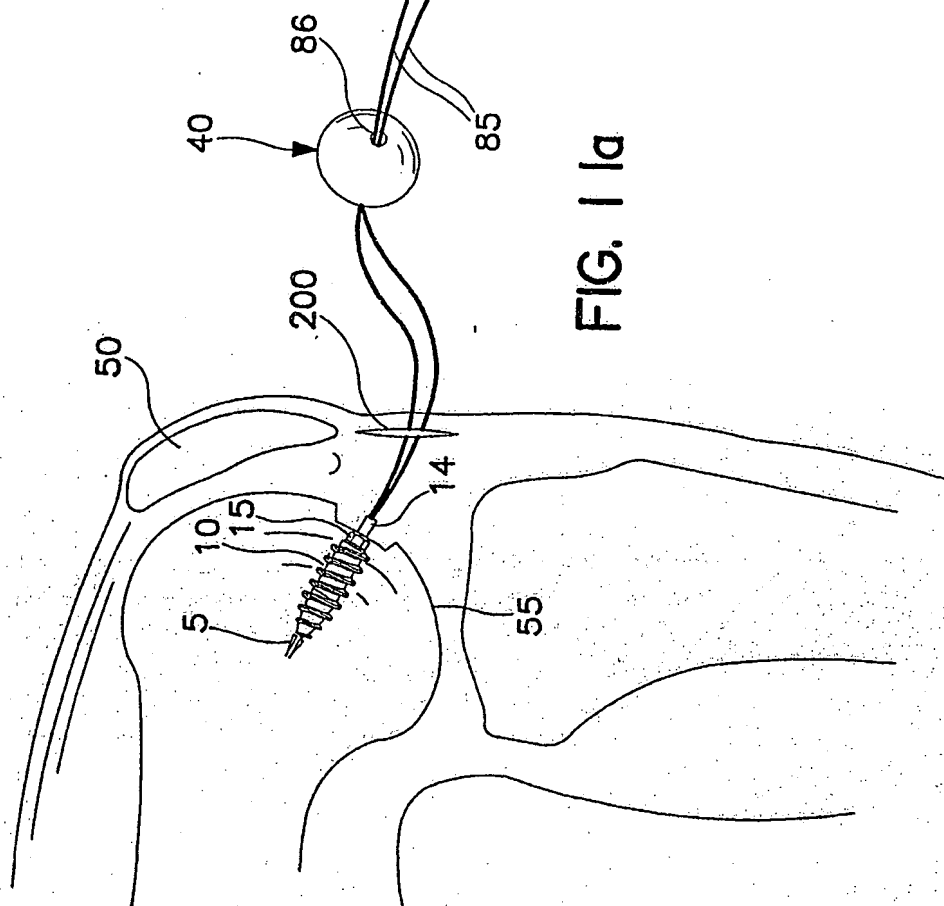
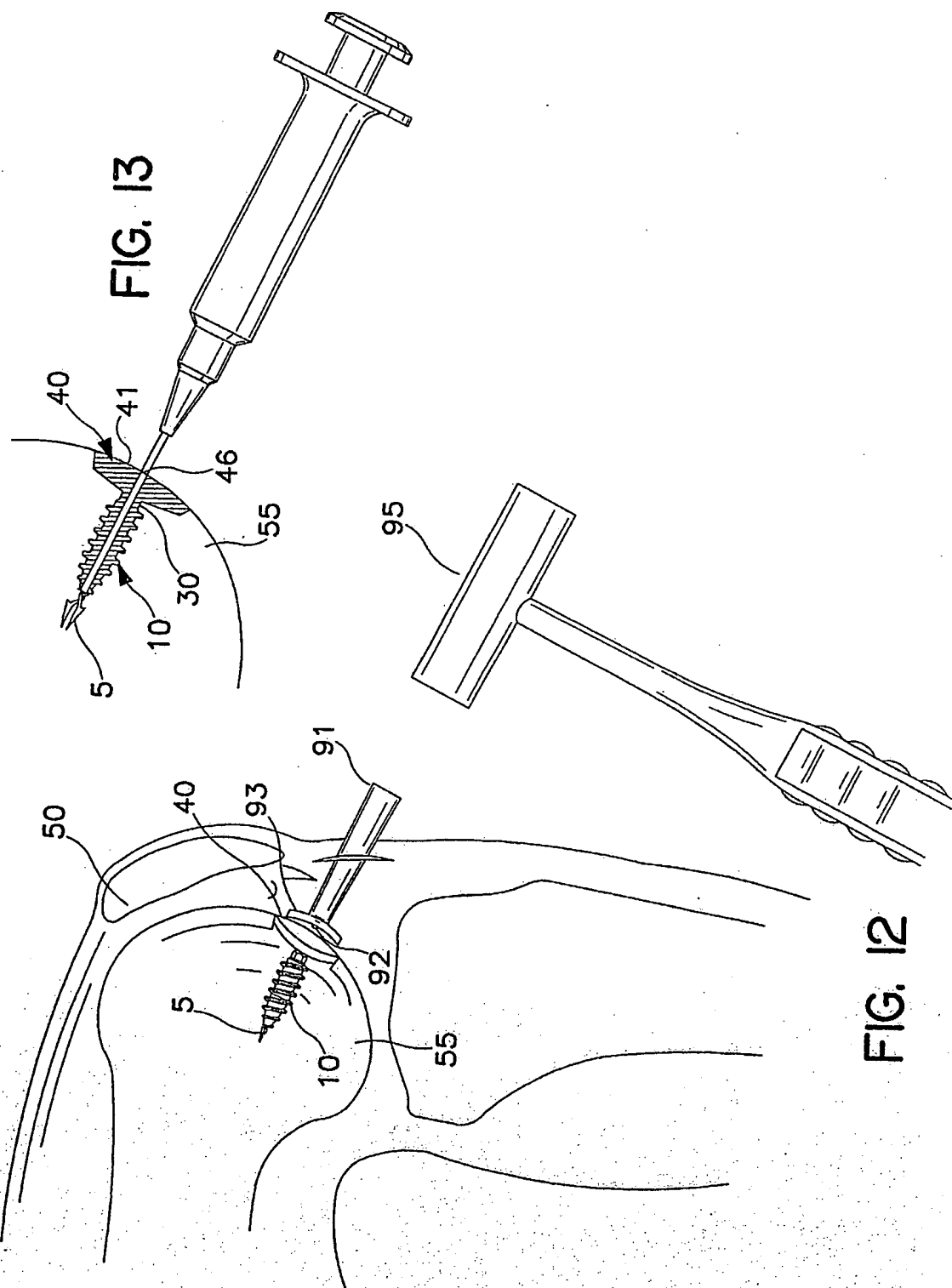


FIG. 1 la

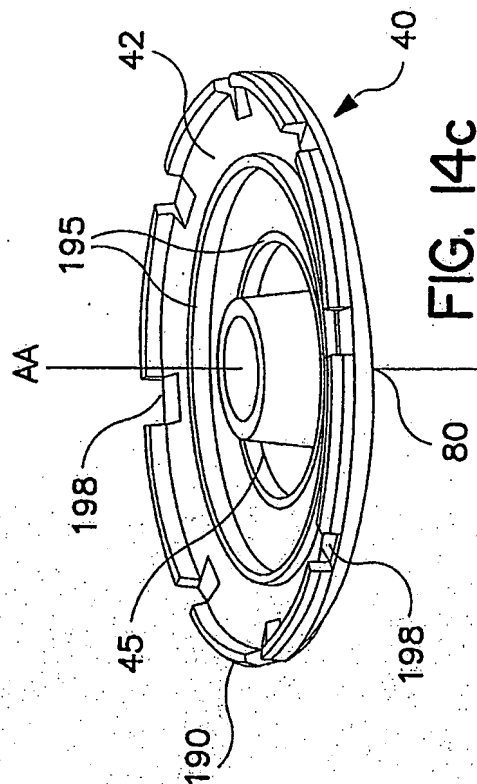
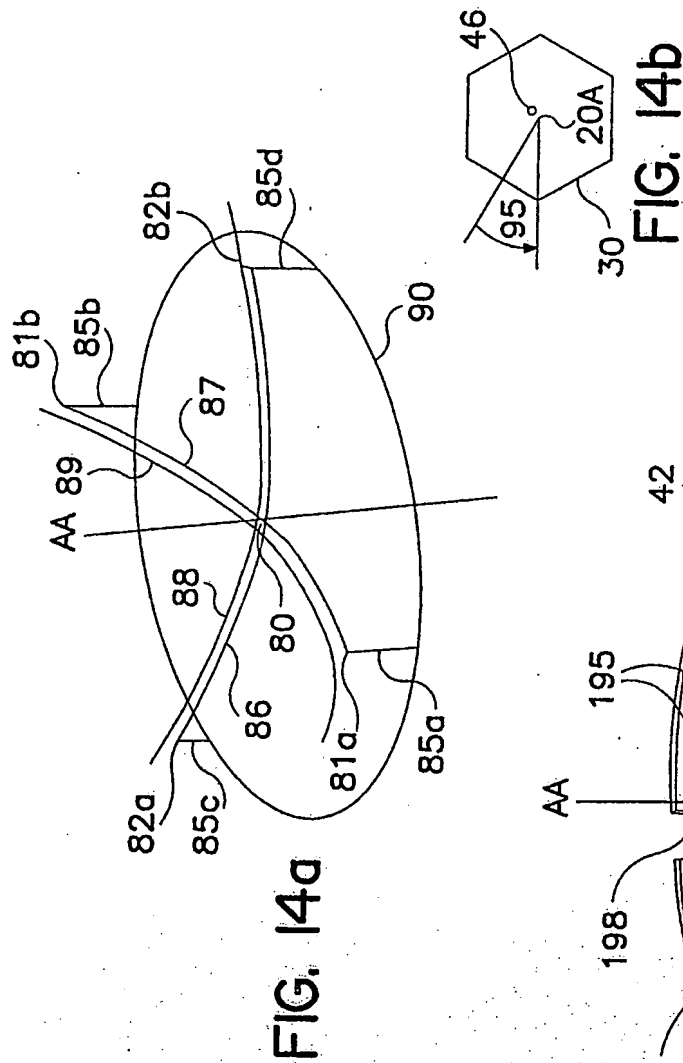


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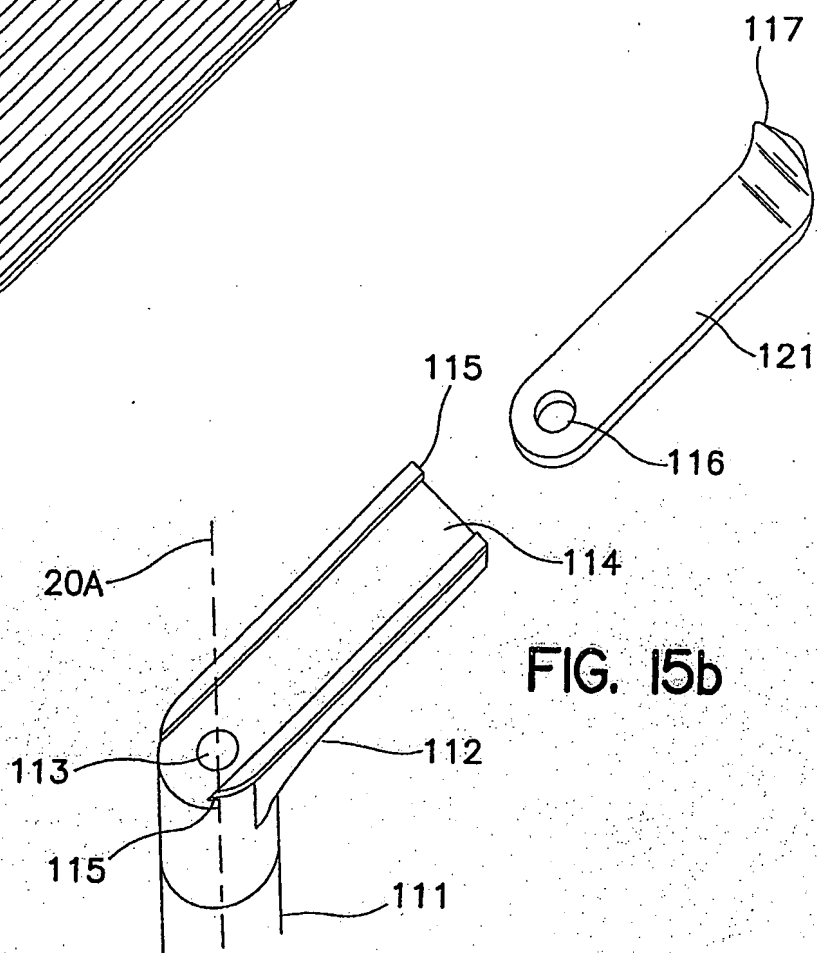
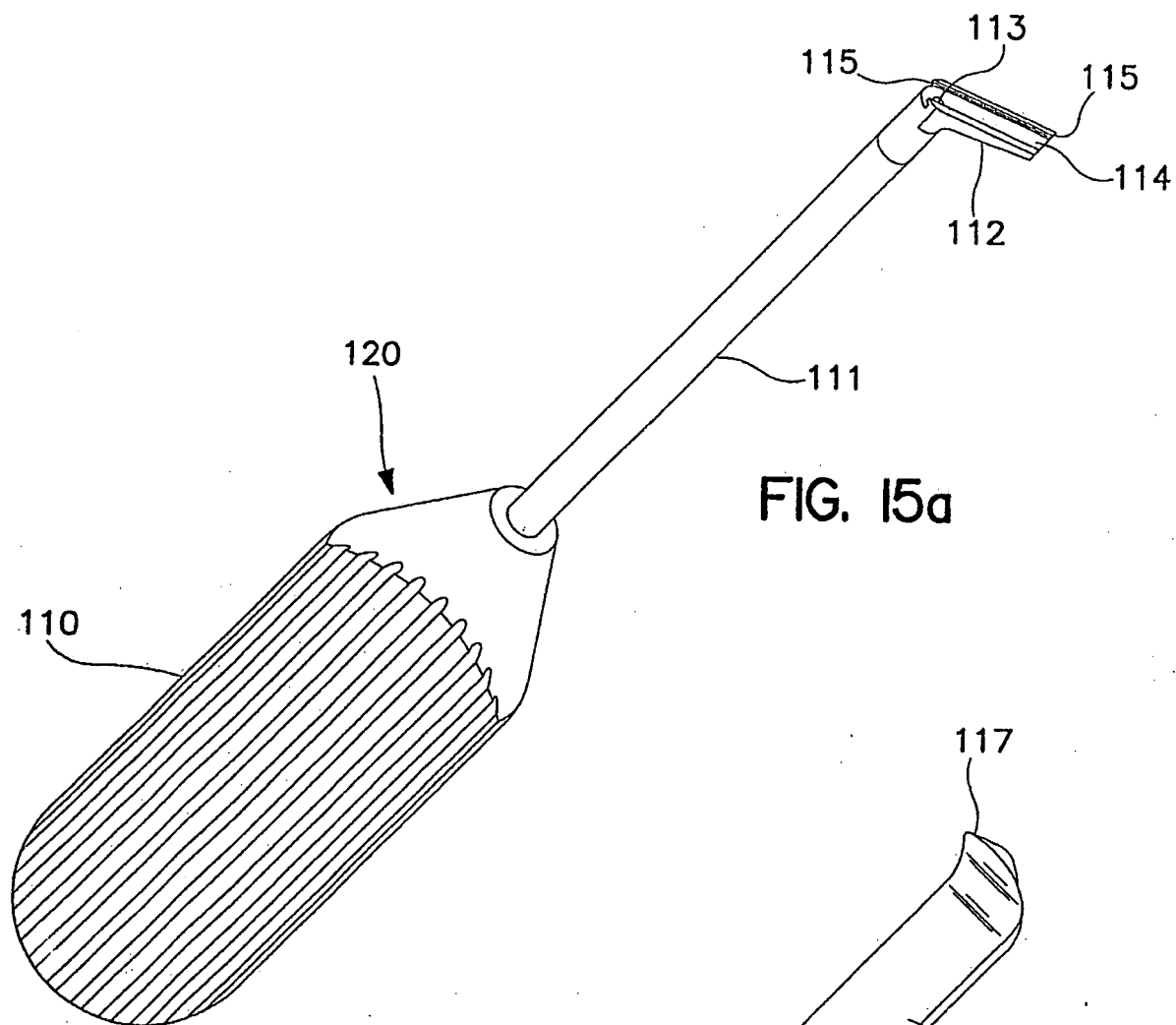




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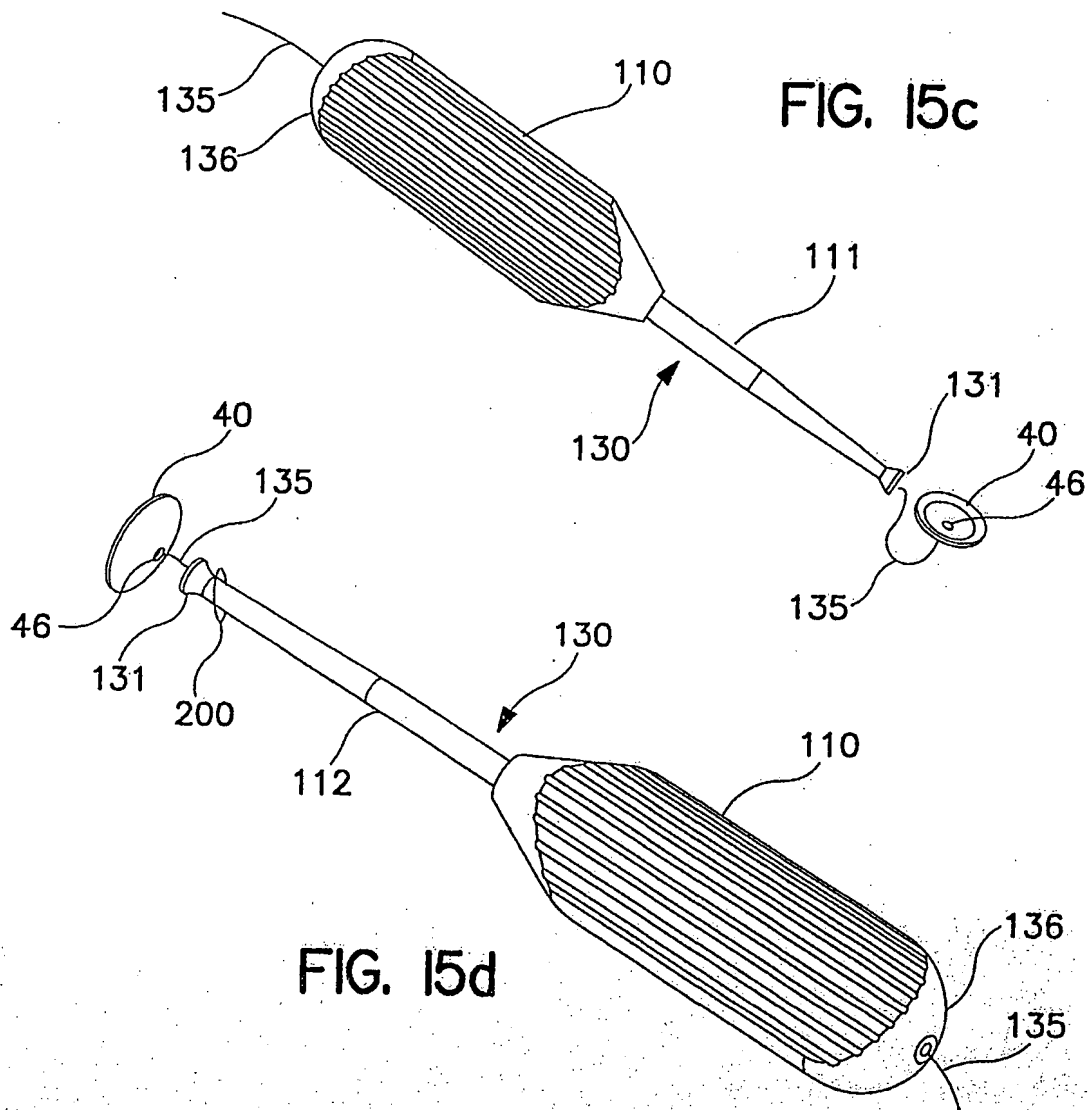


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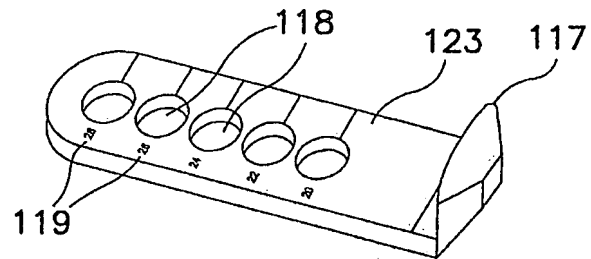


FIG. 17a

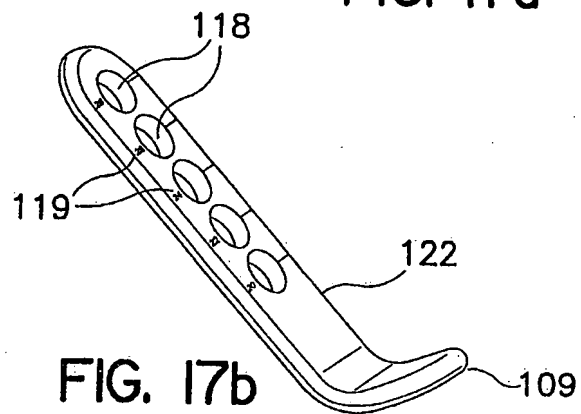


FIG. 17b

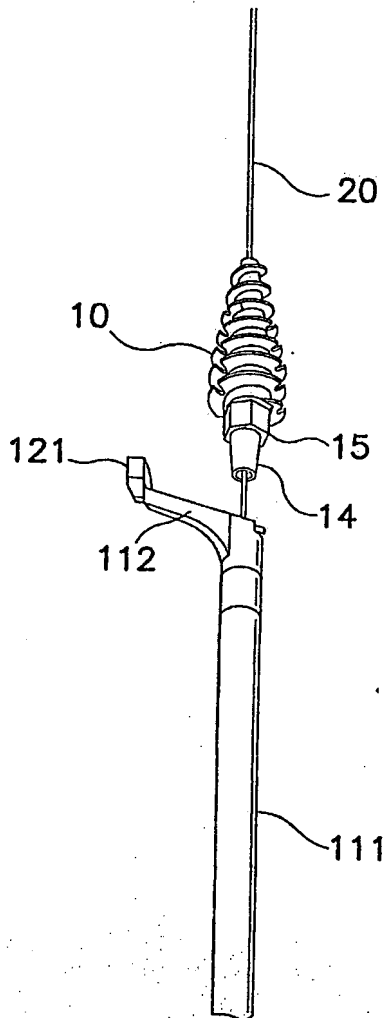


FIG. 16

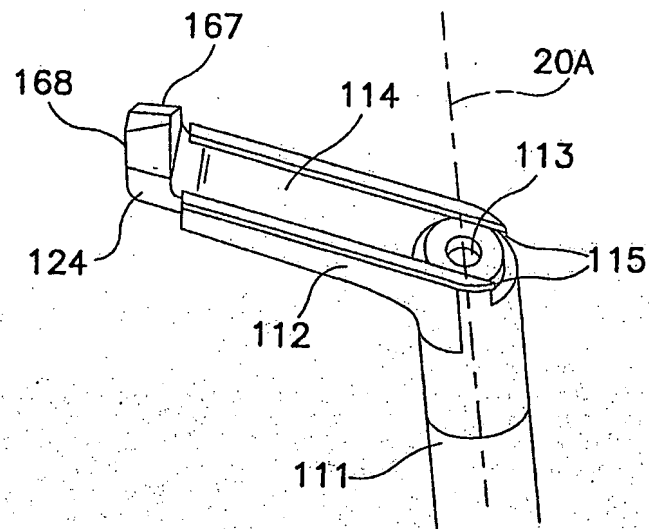


FIG. 17c

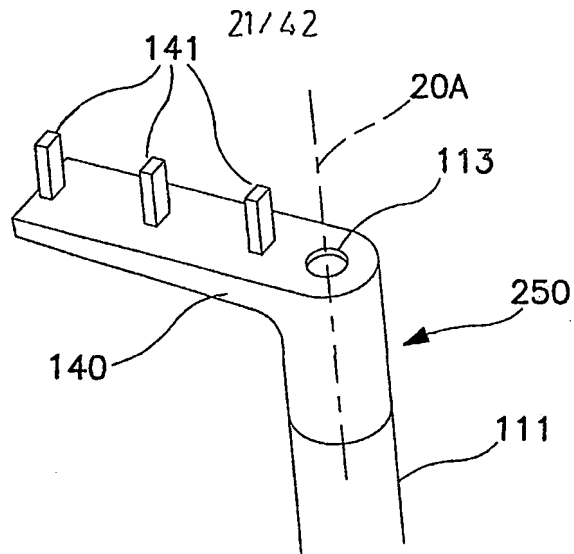


FIG. 18a

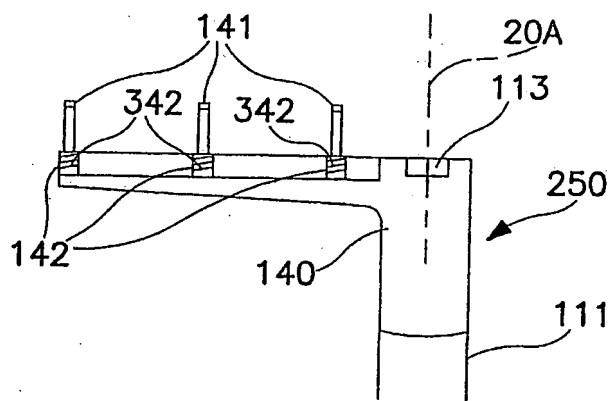


FIG. 18b

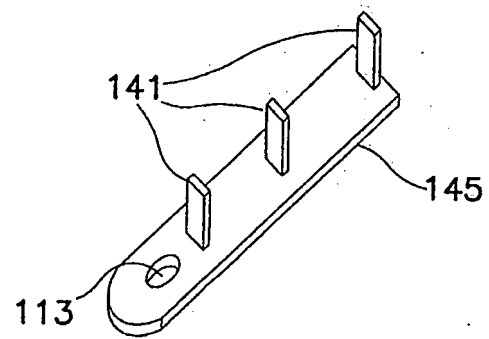


FIG. 18c

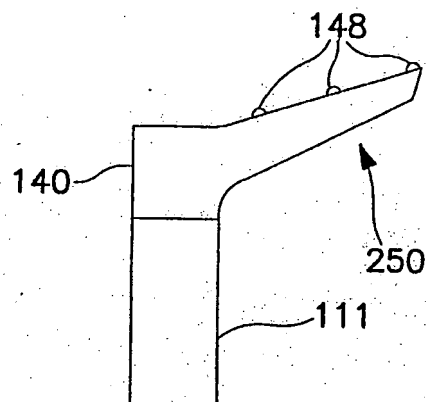


FIG. 18d

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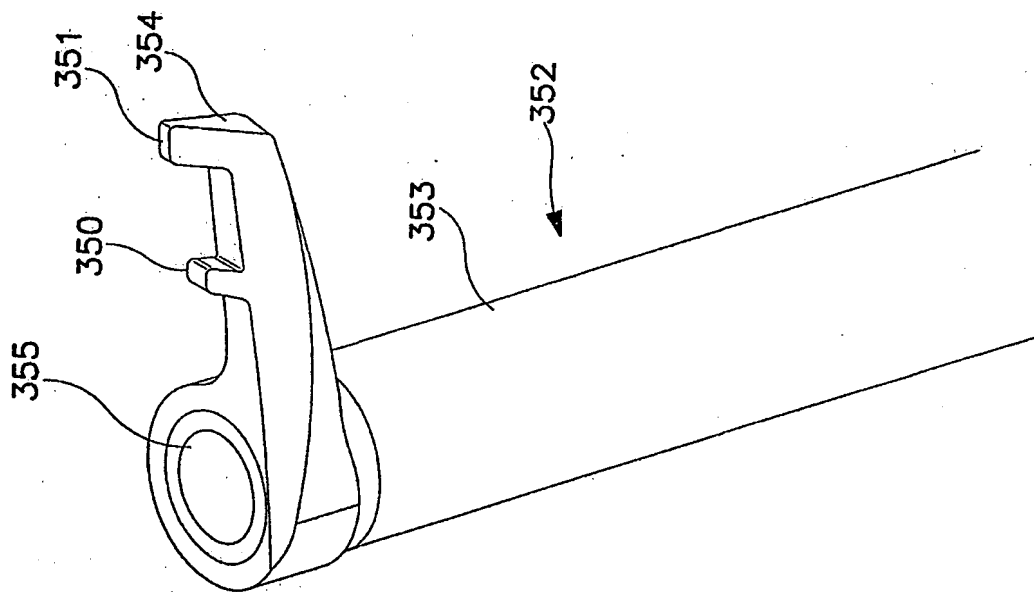
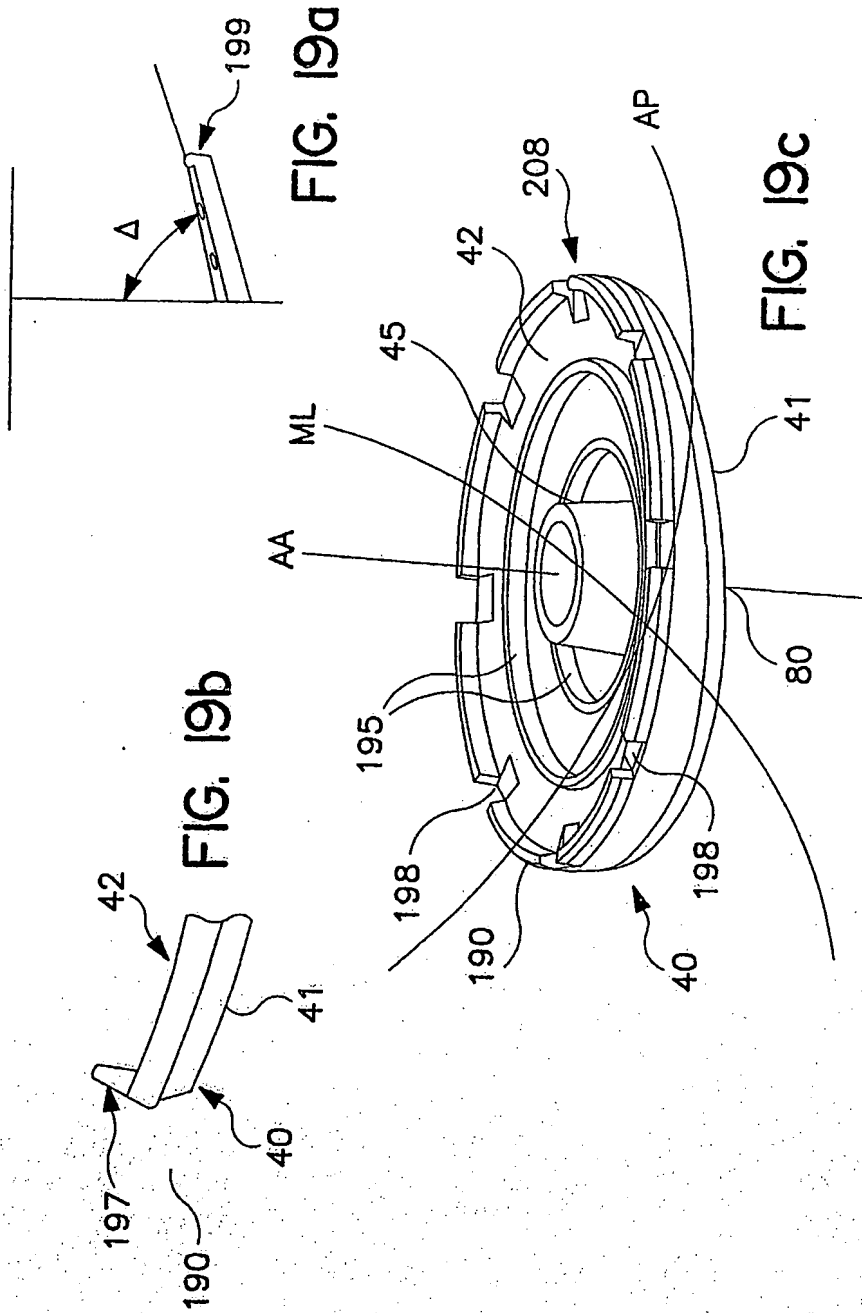


FIG. 18e

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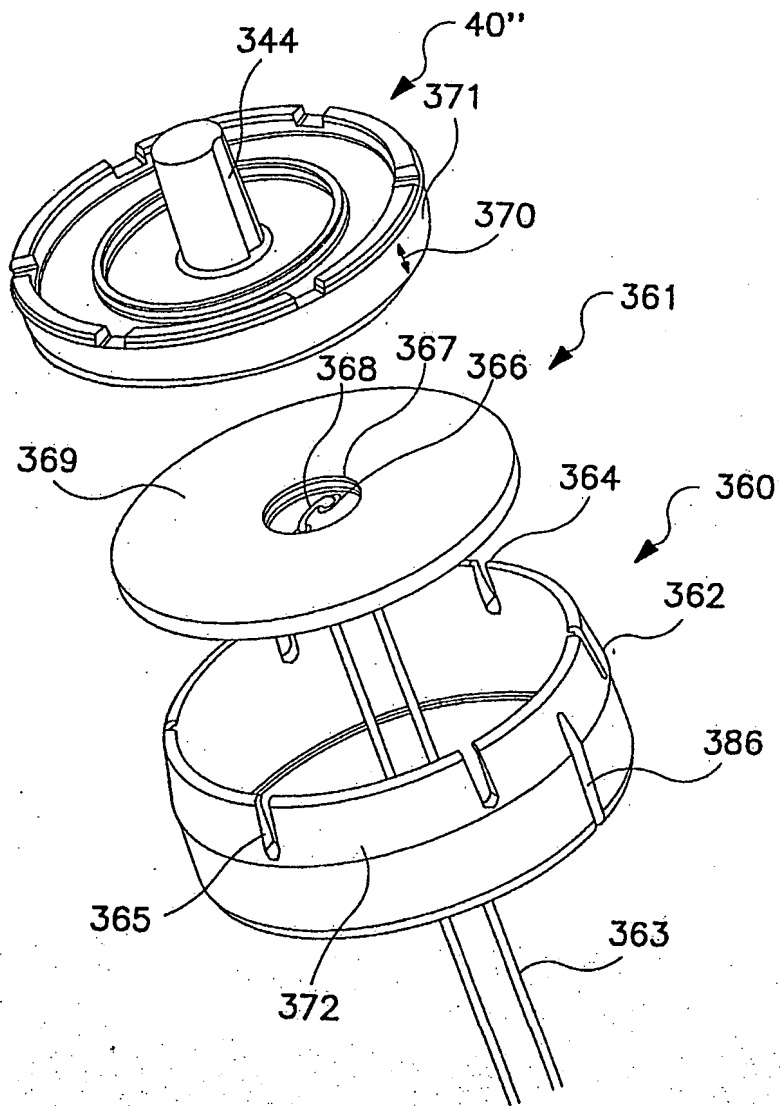


FIG. 19d



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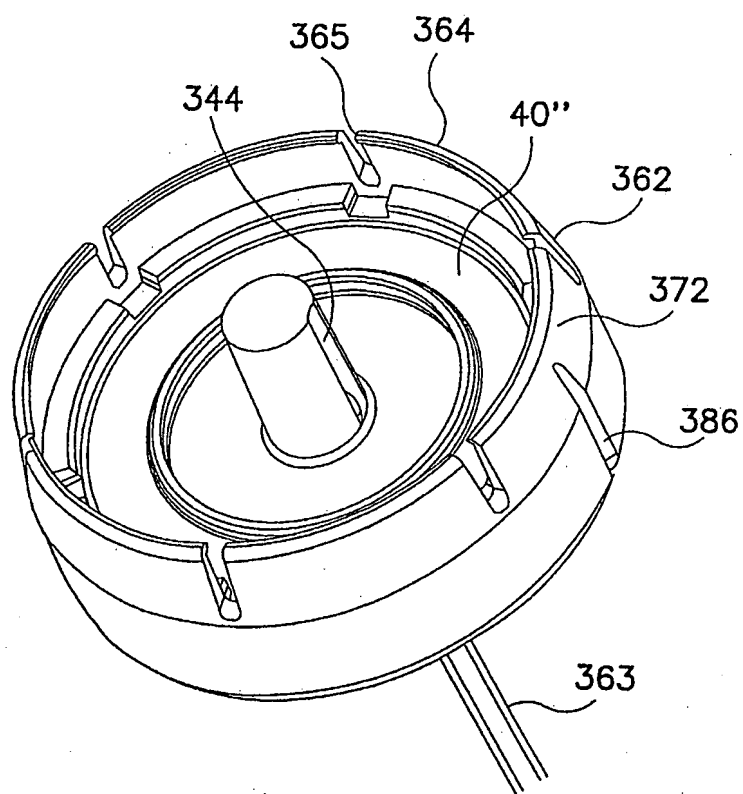
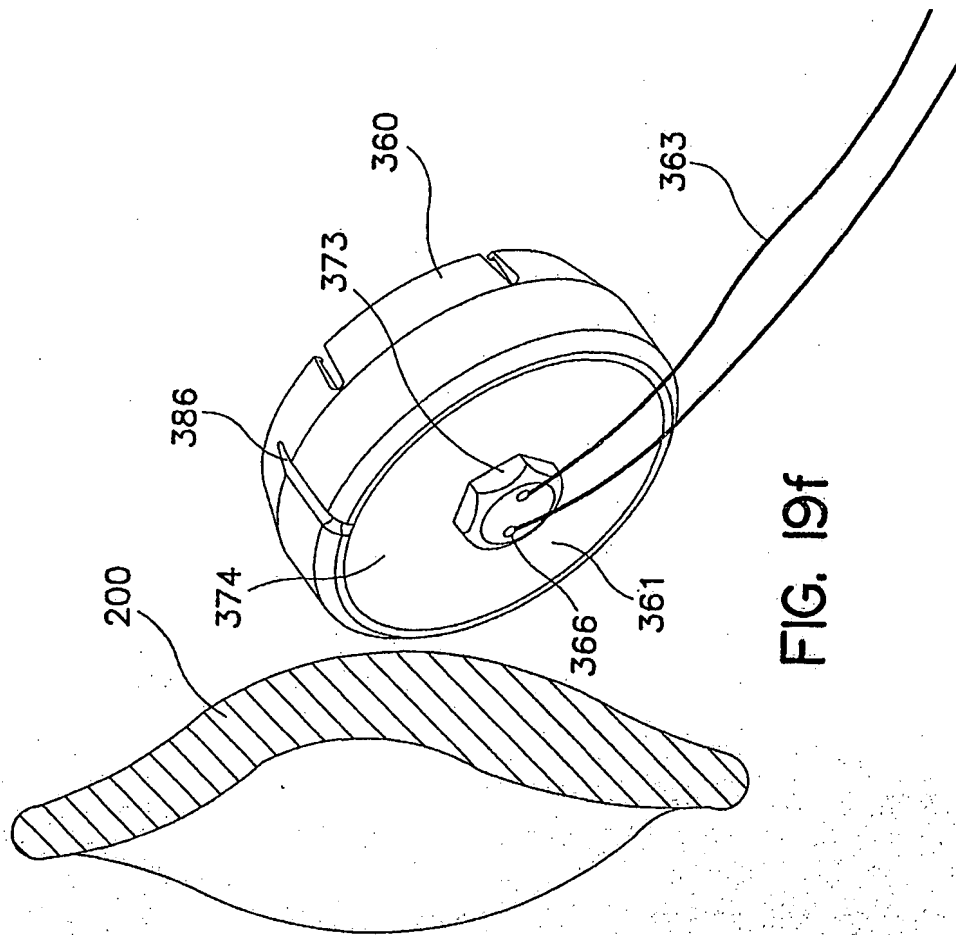


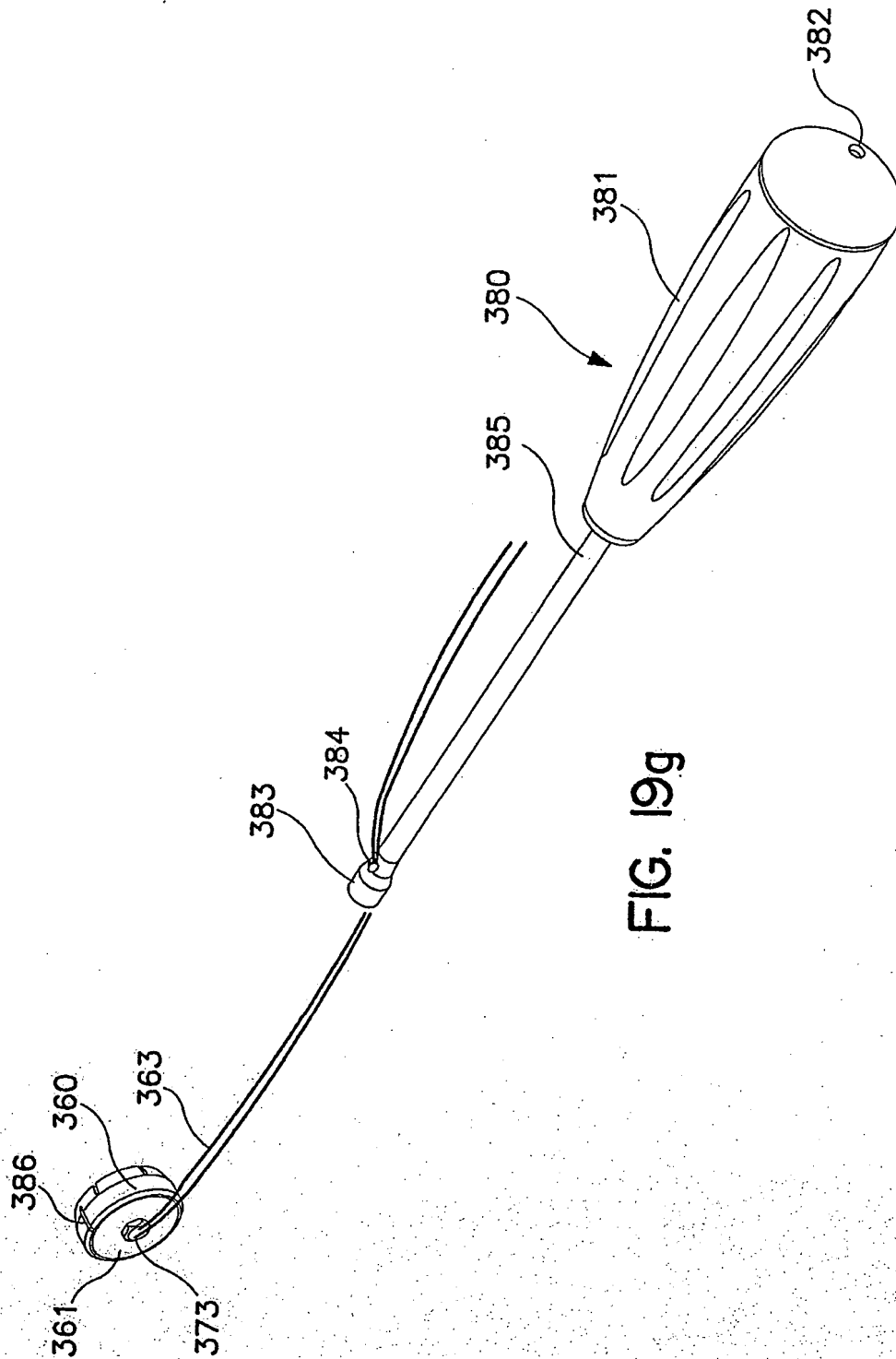
FIG. 19e

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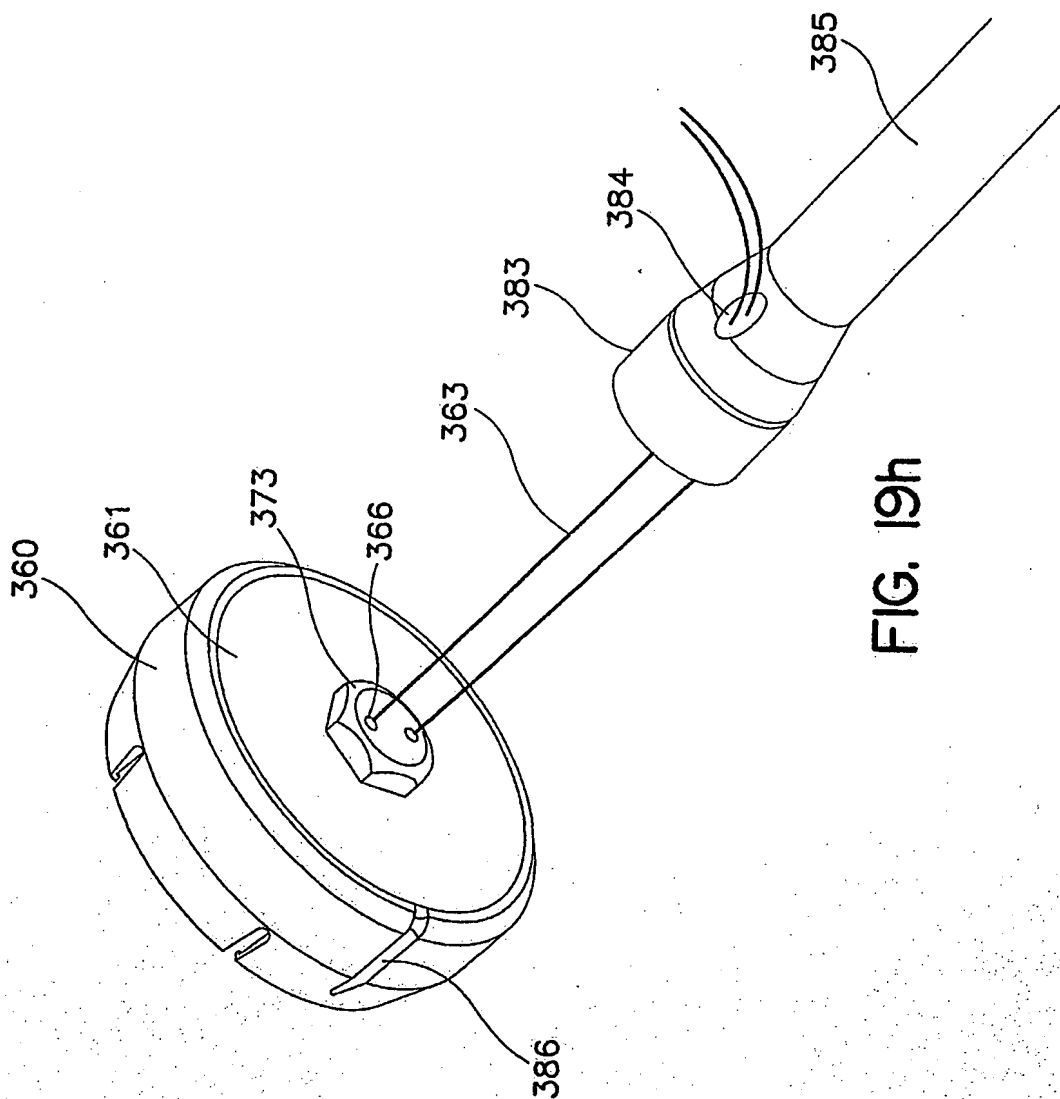
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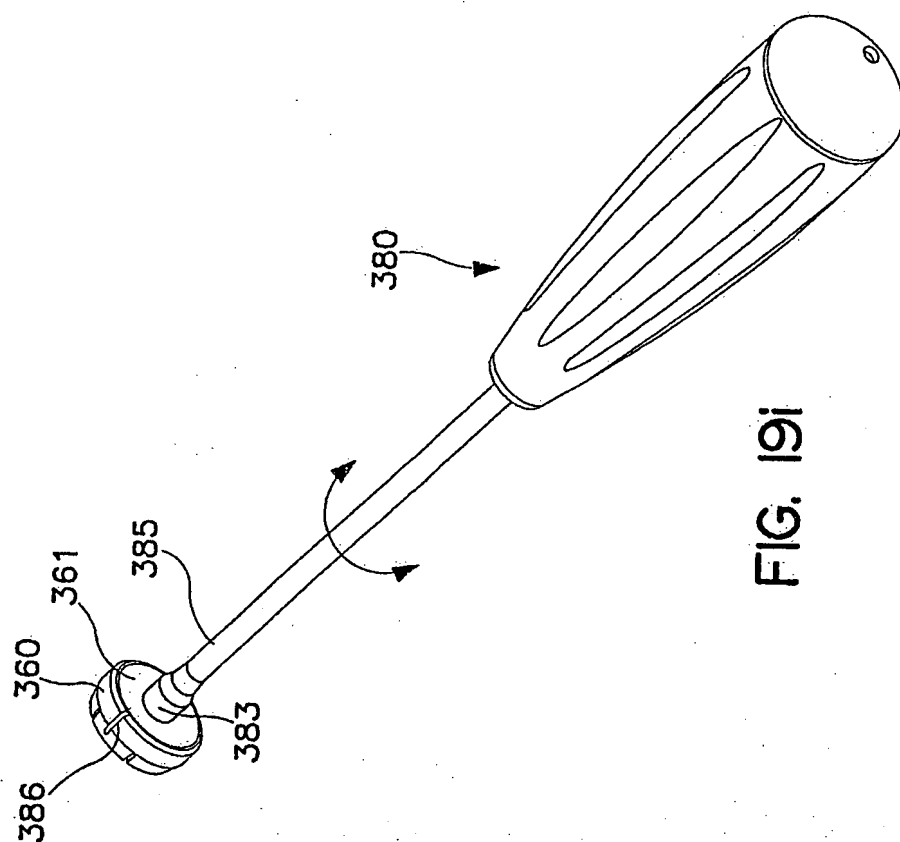


FIG. 19i

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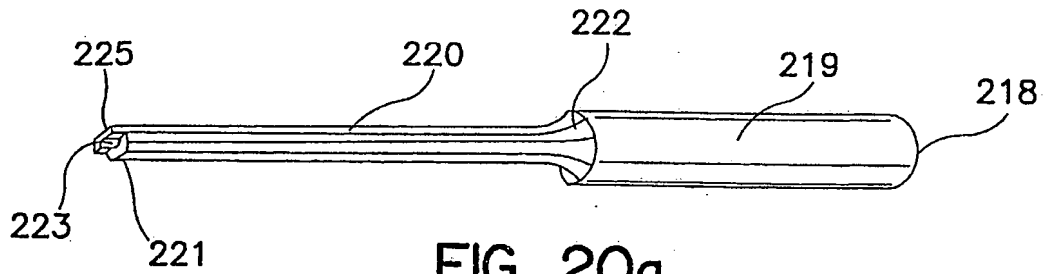


FIG. 20a

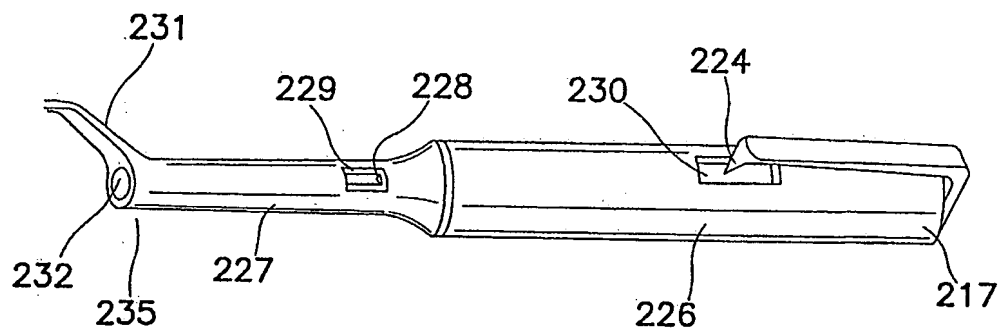


FIG. 20b

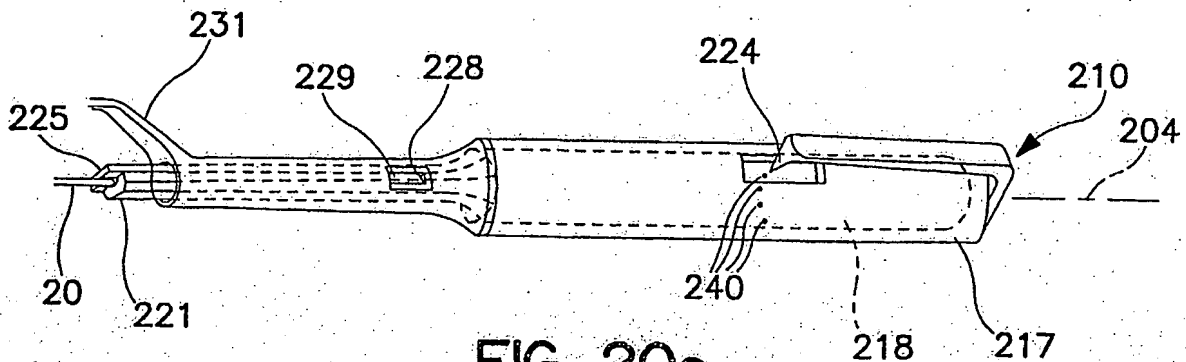


FIG. 20c

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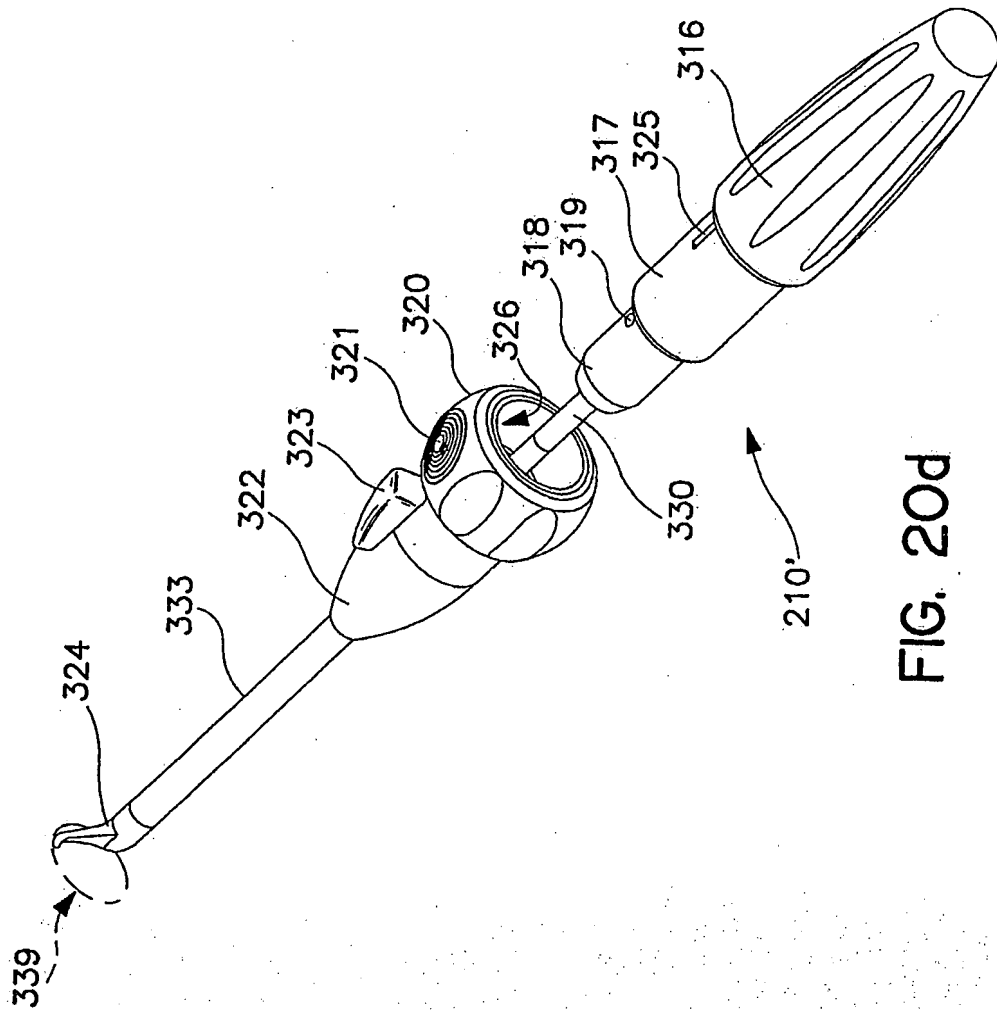
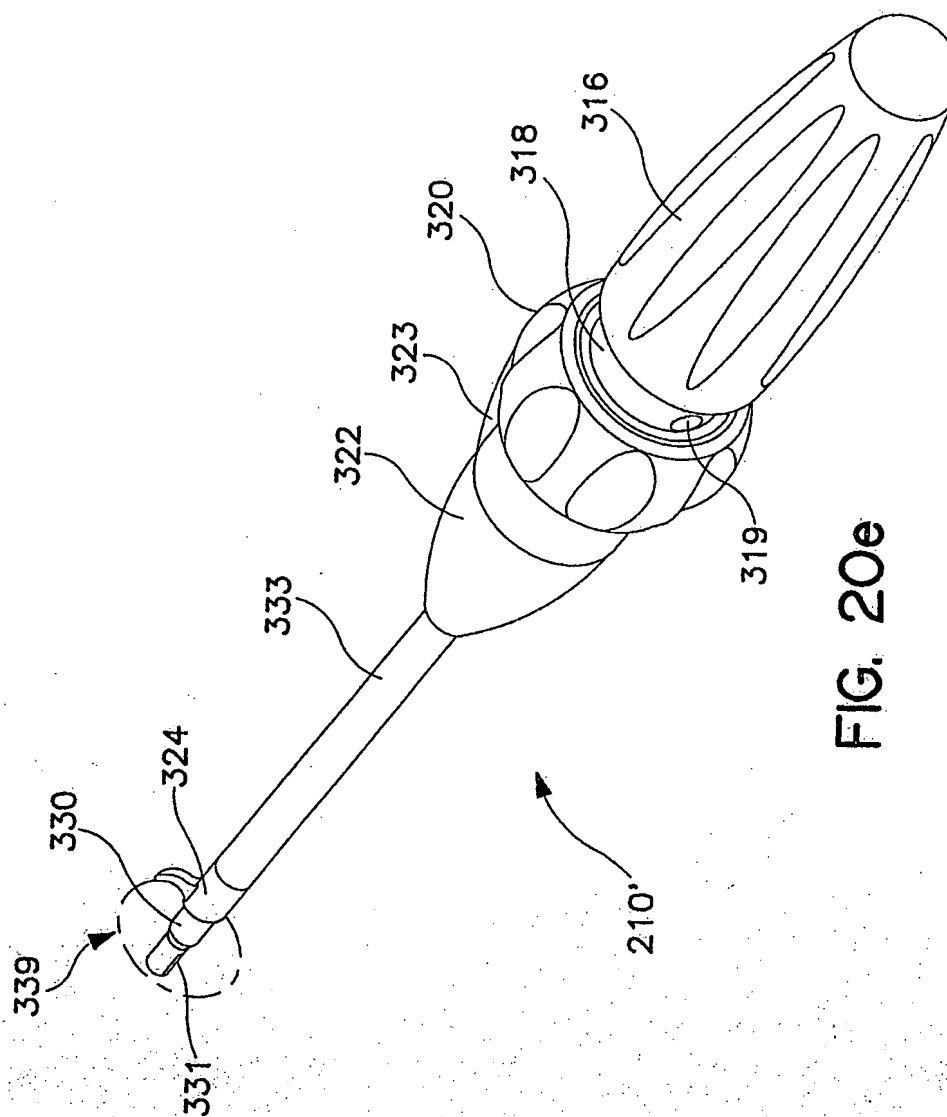


FIG. 20d

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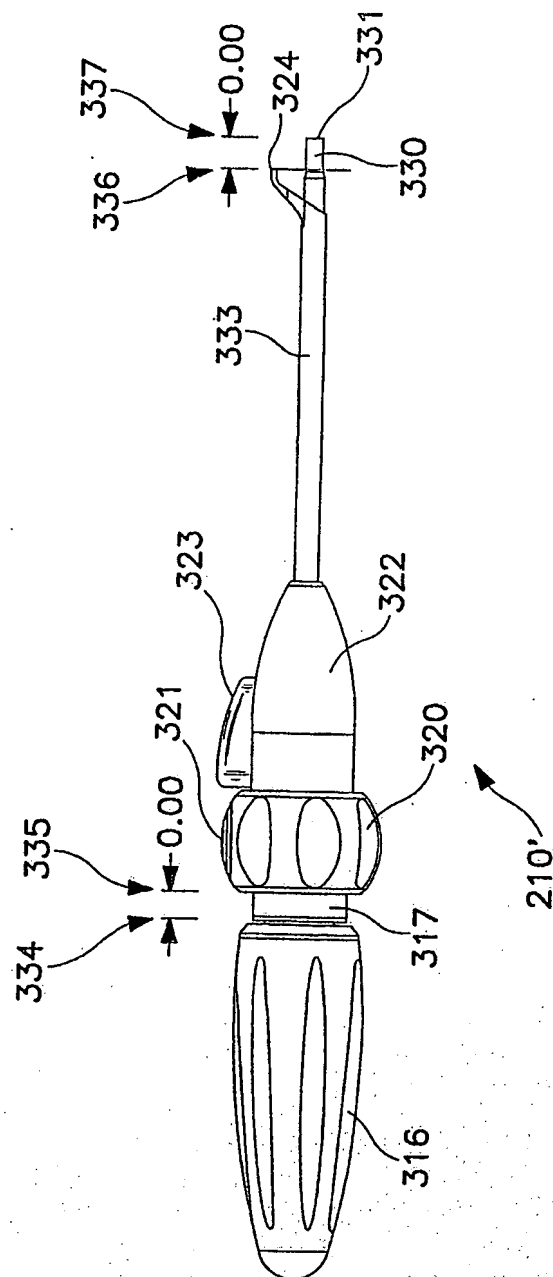


FIG. 20f

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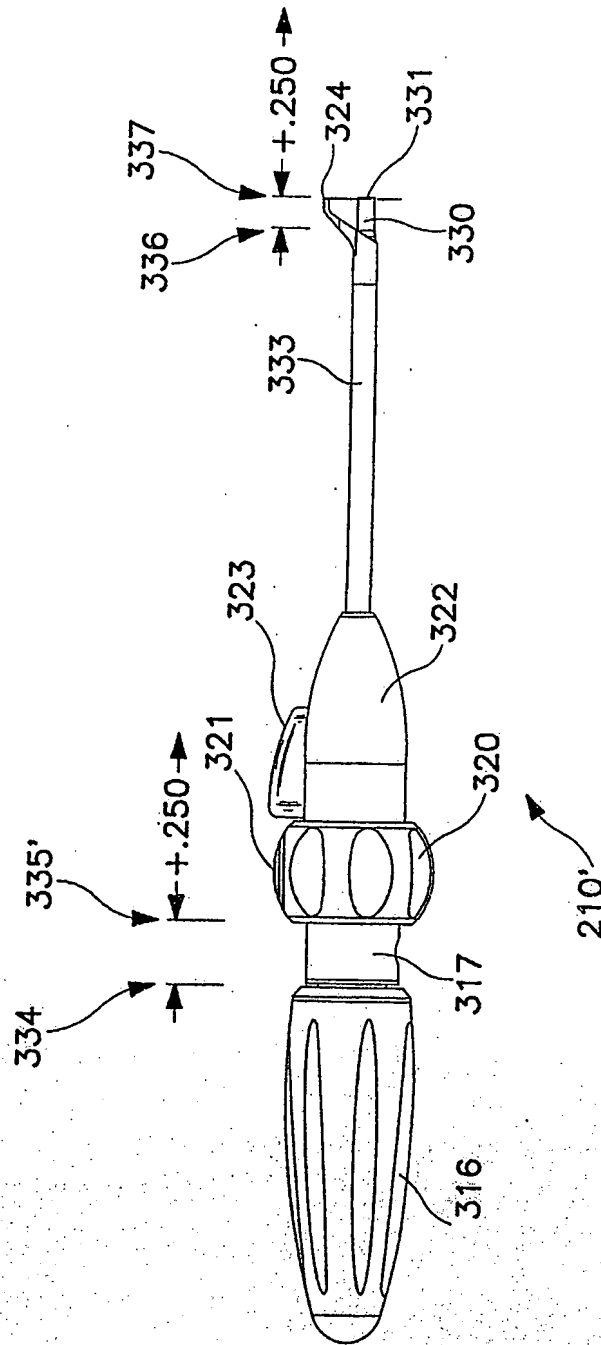
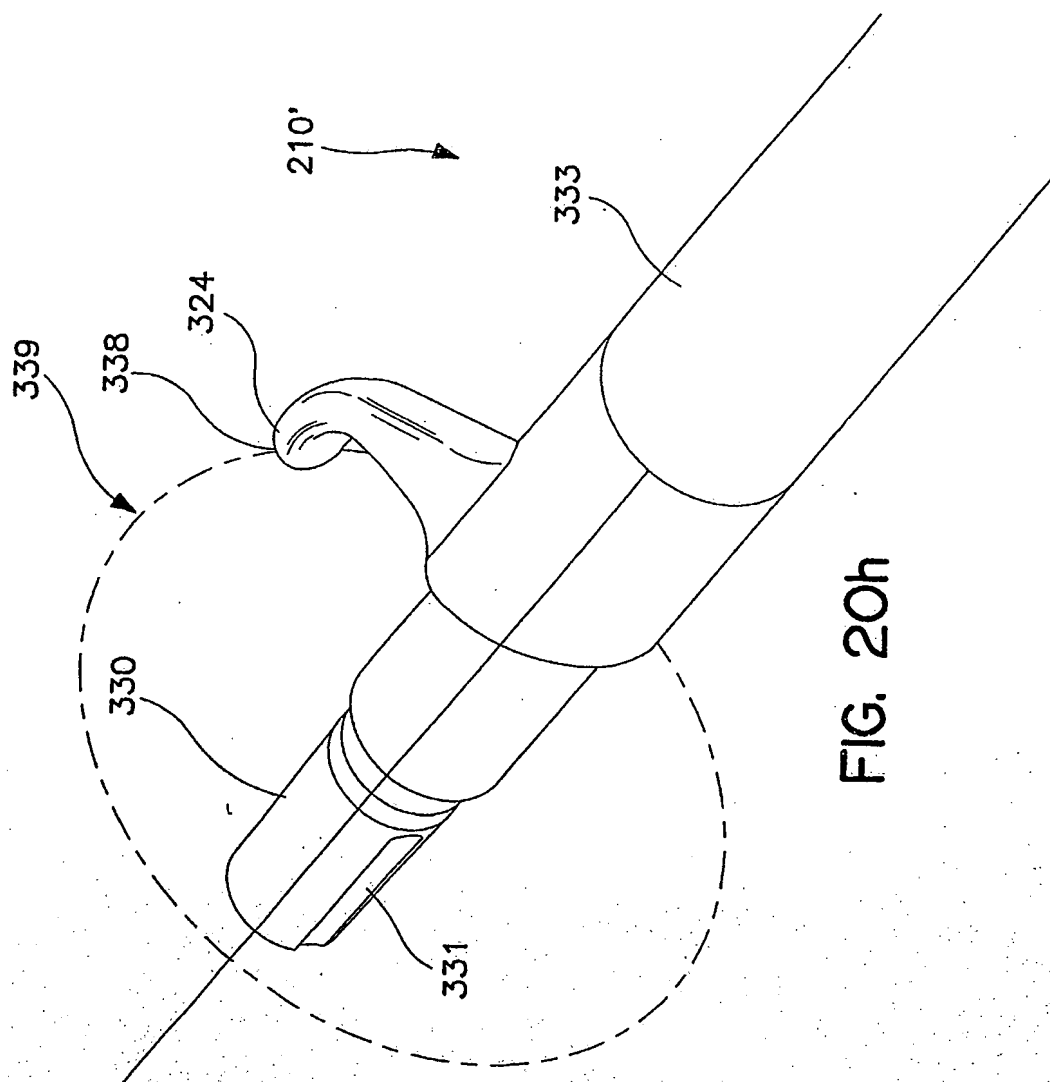


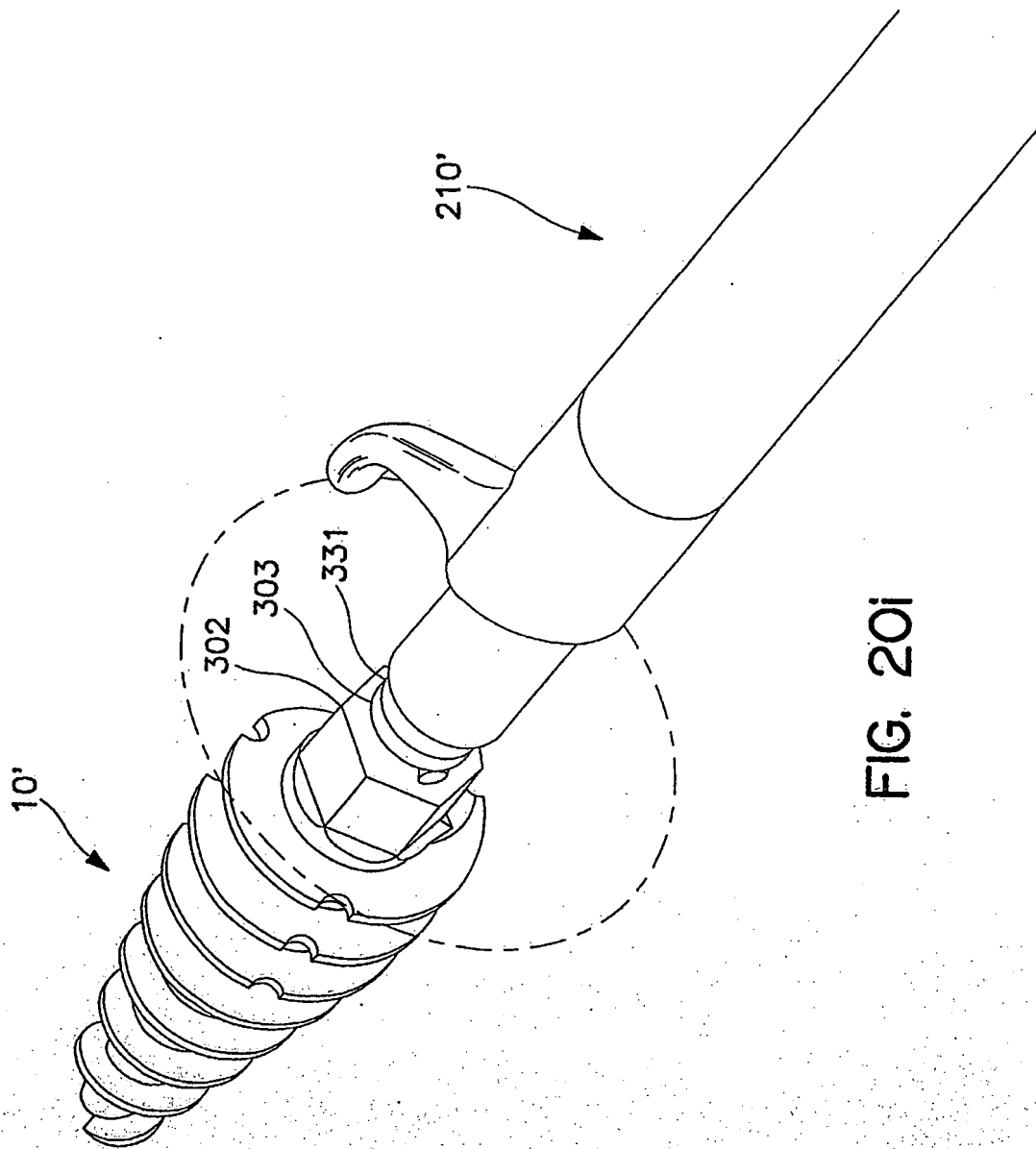
FIG. 20g

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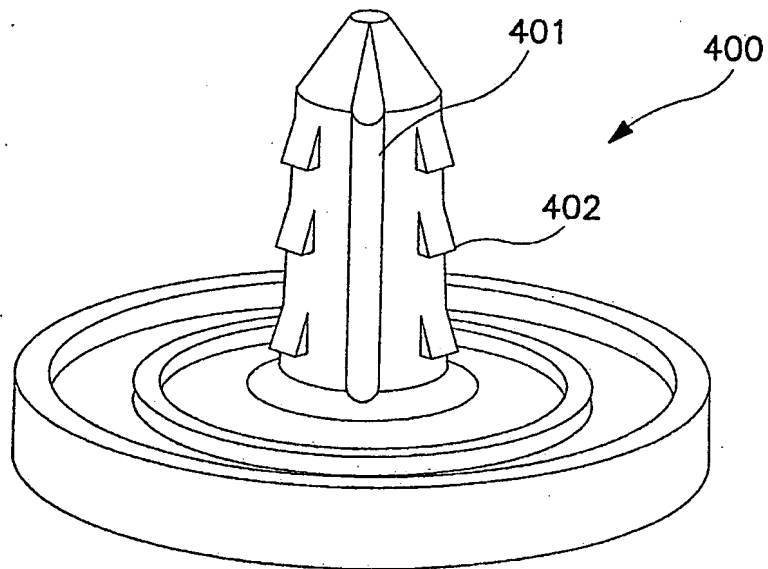


FIG. 21

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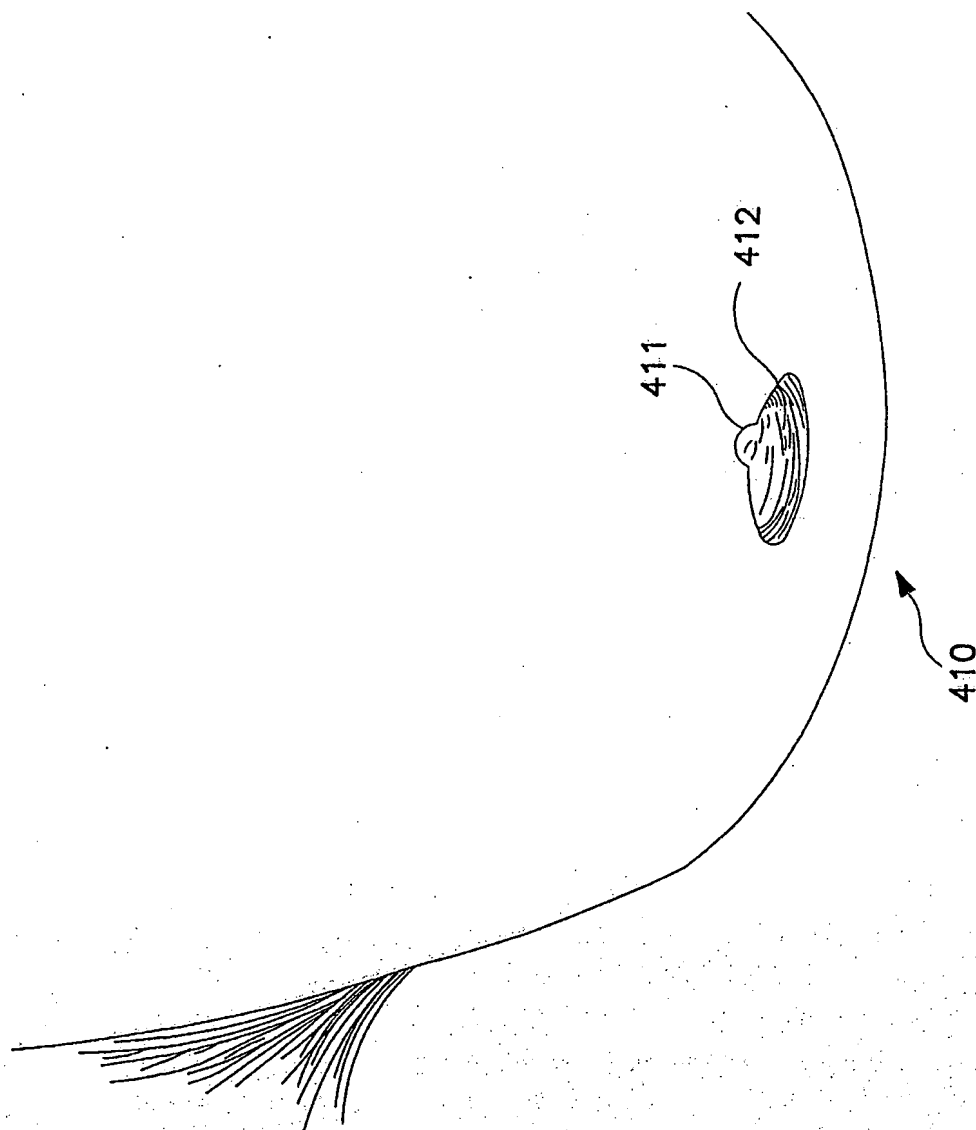


FIG. 22

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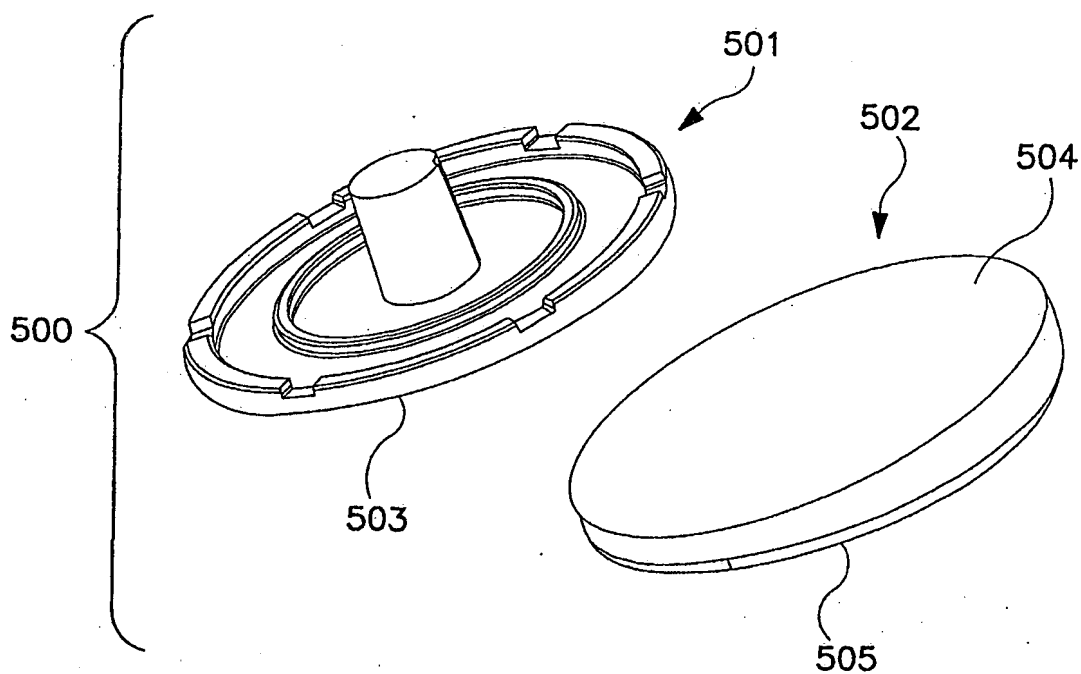


FIG. 23

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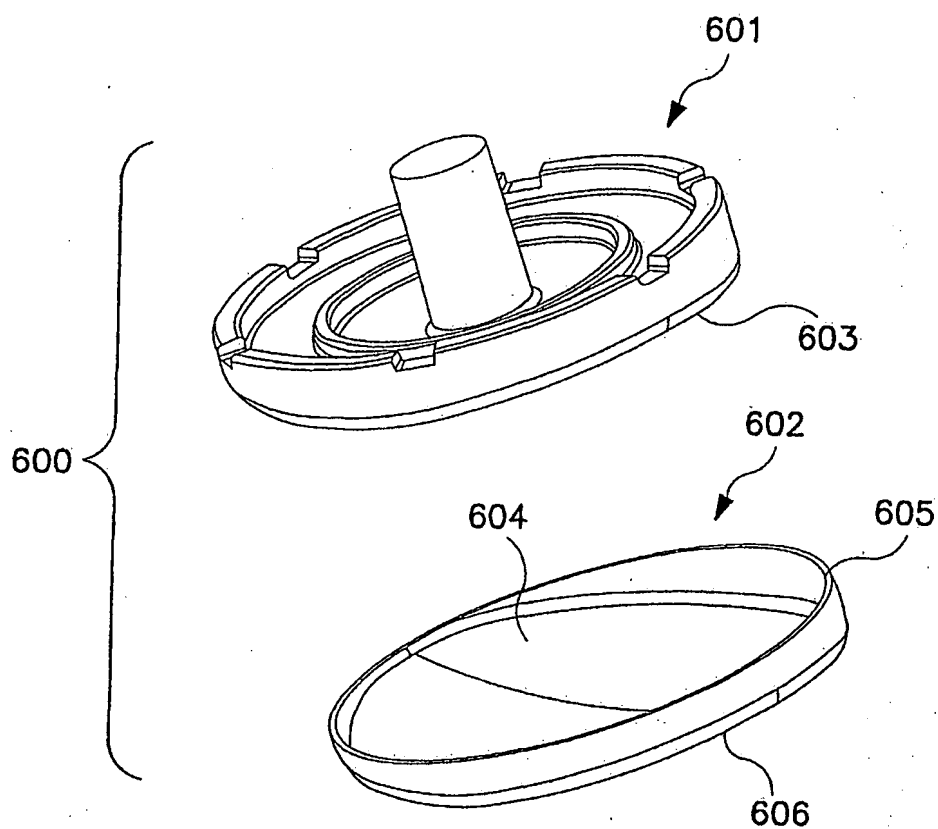


FIG. 24



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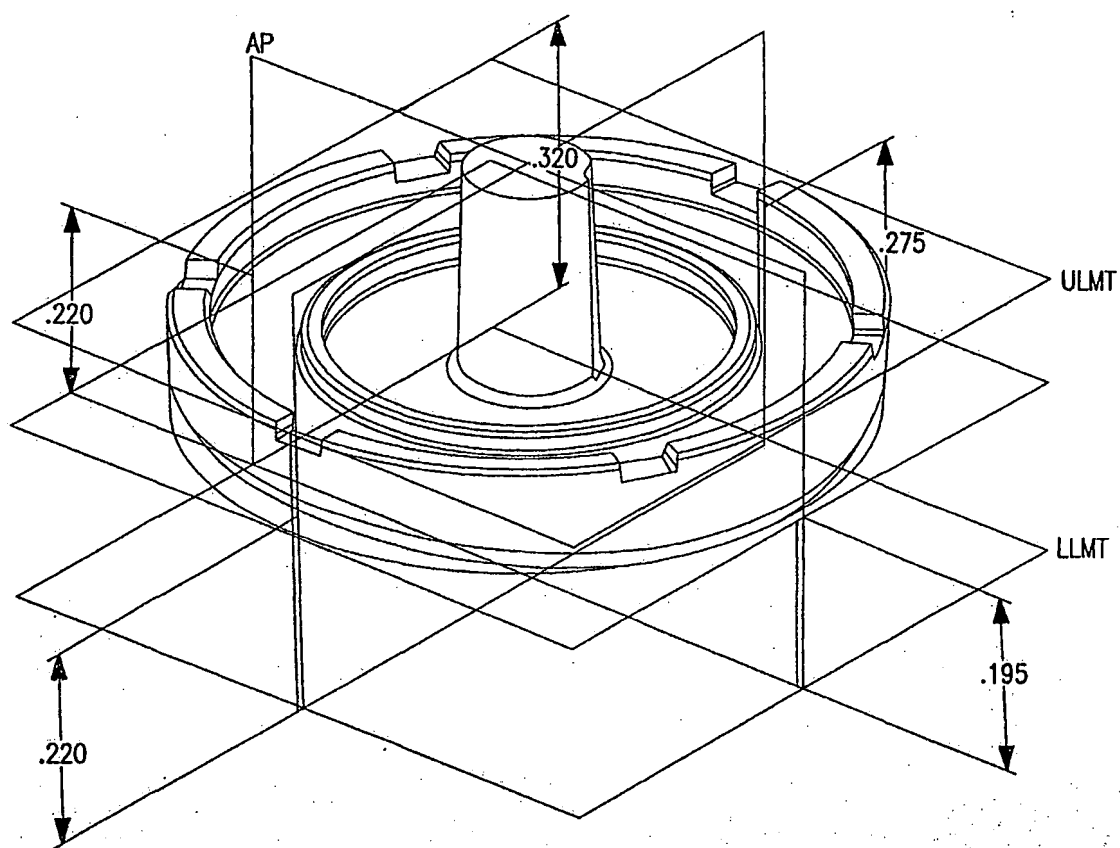


FIG. 25

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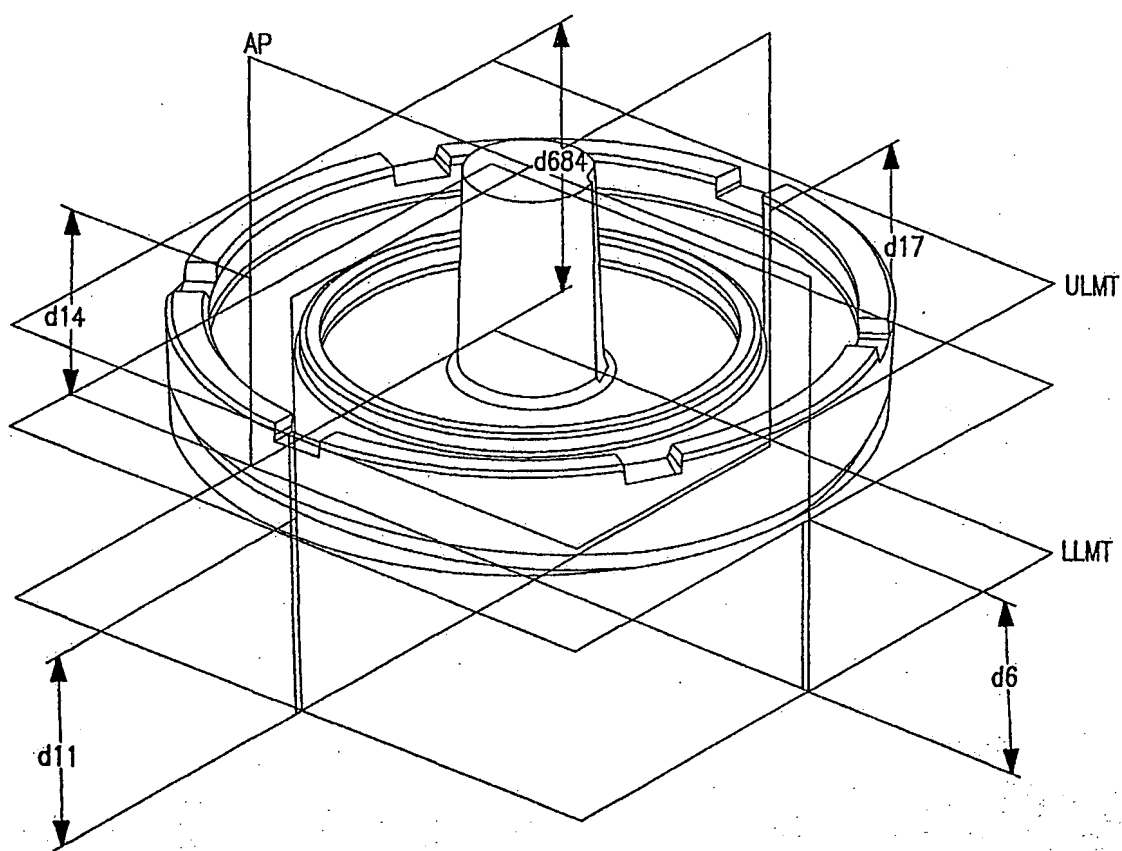


FIG. 26

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
8 November 2001 (08.11.2001)

PCT

(10) International Publication Number  
**WO 01/82677 A3**

(51) International Patent Classification: **A61B 17/00,**  
**A61F 2/46**

Steven, J. [US/US]; 11 Victoria Lane, Mansfield, MA 02048 (US). EK, Steven, W. [US/US]; 49 Powder Hill Road, Bolton, MA 01740 (US).

(21) International Application Number: PCT/US01/14061

(22) International Filing Date: 1 May 2001 (01.05.2001)

(74) Agent: **PFLEGER, Edmund, Paul**; Hayes, Soloway, Hennessey, Grossman & Hage, P.C., 130 W. Cushing Street, Tucson, AZ 85701 (US).

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/201,049 1 May 2000 (01.05.2000) US

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(71) Applicant (*for all designated States except US*): **STD MANUFACTURING, INC.** [US/US]; 1063 Turnpike Street, Box 420, Stoughton, MA 02072 (US).

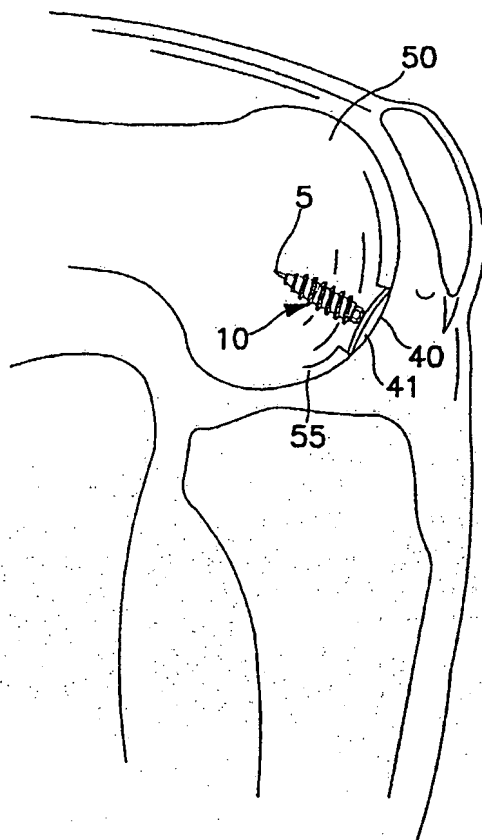
(72) Inventors; and

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW). Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM). European

(75) Inventors/Applicants (*for US only*): **TALLARIDA,**

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR JOINT RESURFACE REPAIR



(57) Abstract: The present invention provides tools and methods for mapping and measuring the articular surface of a joint (or of any bony surface) and for fabricating a prosthetic device based on this recorded data. In one embodiment, once the defect of the chondral surface has been identified, a guide pin (20) is inserted arthroscopically. A fixation screw (10) is driven into the subchondral bone in relation to a reference axis that is approximately central to the defect, the fixation device also serving to define a tangent point to the surrounding articular surface. A measuring tool (70) having a static post that establishes the axial location of origin is inserted on the reference axis. Data recorded during the mapping procedure is entered into parametric engineering design software of similar algorithm to define a three dimensional surface matched to the bearing surface geometry to be implanted and reproduce the anatomic contours mapped.

WO 01/82677 A3



patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,  
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:  
11 April 2002

**Published:**

— with international search report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/14061

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(7) : A61B 17/00; A61F 2/46 US CL : 606/102; 623/18.11, 20.14, 20.31, 23.35 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/102; 623/18.11, 20.14, 20.31, 23.35, 20.31, 20.28, 20.29, 20.33  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	US 5,964,808 A (BLAHA et al) 12 October 1999, whole document.	1-10
Y	US 5,888,210 A (Draenert) 30 March 1999, whole document.	1-10
Y	US 5,771,310 A (Vannah) 23 June 1998, whole document.	1-10
A	US 5,824,105 A (Ries et al) 20 October 1998, whole document.	1-10
A	US 5,486,178 A (Hodge) 23 January 1996, whole document.	1-10
A	US 5,540,696 A (Booth, Jr. et al) 30 July 1996, whole document.	1-10
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle of theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claims, or which is cited to establish the publication date of another citation in other special reason (as specified)	"N"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 14 SEPTEMBER 2001	Date of mailing of the international search report 27 DEC 2001	
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PAUL J. HIRSCH Telephone No. (703) 308-0858	

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/14061

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,928,286 A (Ashby et al) 27 July 1999, whole document.	3-5

Form PCT/ISA/210 (continuation of second sheet) (July 1998)\*

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 728 162 A (ECKHOFF DONALD G [US]) 17 March 1998 (1998-03-17)	1-3, 6-8, 10, 11, 18; 22-24, 28, 29, 33, 34	INV. A61F2/38 A61F2/30
Y	* column 3, line 24 - column 4, line 23 * * figures 2, 3 *	4, 5, 9, 12, 15-17, 19-21	
X	US 5 133 759 A (TURNER RICHARD H [US]) 28 July 1992 (1992-07-28)	28, 29, 33, 34	
Y	* column 2, line 40 - line 68 * * figure 7 *	4, 5, 9, 12, 15-17, 20, 21	
Y	US 6 165 221 A (SCHMOTZER HANS [CH]) 26 December 2000 (2000-12-26) * column 3, line 50 - line 56 * * figures 6, 7 *	19	TECHNICAL FIELDS SEARCHED (IPC)  A61F
-/--			
<b>LACK OF UNITY OF INVENTION</b>			
<p>The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:</p> <p>see sheet B</p> <p>The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.</p>			
Place of search	Date of completion of the search		Examiner
Munich	October 2007		Storer, John
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			



European Patent  
Office

SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT

Application Number  
EP 04 81 2273

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IPC)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	WO 01/82677 A (STD MFG INC [US]; TALLARIDA STEVEN J [US]; EK STEVEN W [US]) 8 November 2001 (2001-11-08) * page 15, line 21 - line 26 * * page 26, line 26 - page 27, line 15 * * figure 1 *	27	
X	WO 02/096268 A2 (IMAGING THERAPEUTICS [US]; LANG PHILIPP [US]; LINDER BARRY [US]; STEIN) 5 December 2002 (2002-12-05) * page 8, line 1 - line 23 * * page 9, line 20 - line 29 * * page 32, line 1 - line 25 * * claim 57 * * figures 8A-8H, 11A, 11B *	27	
			TECHNICAL FIELDS SEARCHED (IPC)





The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-24,27-29,33,34

An implant suitable for a condyle of a femur having a superior surface and an inferior surface, wherein the superior surface opposes at least a portion of the condyle of the femur and the trochlea and the inferior surface opposes at least a portion of a weight bearing portion of a tibial surface and a patella, and further wherein at least a portion of one of the superior or inferior surfaces has a three-dimensional shape that substantially matches the shape of one of the femur and tibial surfaces.

----

2. claims: 25,26,30-32,35

A prosthetic device for a knee joint comprising:  
a femoral condyle component having a superior surface and an inferior surface and a top portion and a bottom portion with a curved surface extending therebetween; and  
a trochlear groove component along the top portion of the device, wherein the bottom portion of the femoral condyle component terminates after a sulcus terminalis.

----

3. claims: 36,37

A tibial component having a first surface having a substantially planar surface and a second surface with a partially planar surface wherein the second surface with a partially planar surface further comprises a dome structure.

----

The common concept linking group of claims 1-24,27-29,33,34 and group of claims 25,26,30-32,35 is a prosthetic device for a knee joint comprising a superior surface, an inferior surface and a trochlear groove component.

This concept, however, is well known in the state of the art as exemplified in US-A-5728162. There is no common or corresponding "special technical feature" in terms of Rule 30 EPC linking group of claims 1-24,27-29,33,34 and group of claims 25,26,31,32,35, therefore the requirement for unity according to Article 82 EPC is not fulfilled.

The common concept linking group of claims 1-24,27-29,33,34 and group of claims 36,37 is merely an implant. This concept is well known in the state of the art as exemplified in US-A-5728162. There is no common or corresponding "special technical feature" in terms of Rule 30 EPC linking group of claims 1-24,27-29,33,34 and group of claims 36,37, therefore the requirement for unity according to Article 82 EPC is again not fulfilled.



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08.10.07

Reference 115-023PEP	Application No./Patent No. 04812273.3 - 2310 PCT/US2004039714
Applicant/Proprietor Conformis, Inc.	

### Communication

The European Patent Office herewith transmits the partial supplementary European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the supplementary search report are enclosed.

The applicant's attention is drawn to the following:

The Search Division informs the applicant that if the supplementary European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within one month after notification of this communication.

For applications with an international filing date up to 30 June 1999, the amount payable for a search fee requested under Rule 46(1) EPC is EUR 869,-- (OJ EPO 2006, 495).

For applications with an international filing date between 1 July 1999 and 30 June 2005, the amount payable for a search fee requested under Rule 46(1) EPC is EUR 720,-- (OJ EPO 2006, 495).

☒ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

### Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement No.2 to Official Journal No.01/2005.



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**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 81 2273

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

01-10-2007

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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